IN THE COURT OF COMMON PLEAS SUMMIT COUNTY, OHIO

MEMBER WILLIAMS, et al.,

Plaintiffs,

vs.

KISLING, NESTICO & REDICK, LLC, et al.,

Defendants.

Case No. CV-2016-09-3928

Judge James A. Brogan

Notice of Filing Volume V of Exhibits to the Deposition of Defendant Sam Ghoubrial

Plaintiffs hereby give notice of filing Volume V of exhibits to the deposition of Defendant Sam Ghoubrial, taken on April 9, 2019.

Respectfully submitted,

/s/ Rachel Hazelet

Peter Pattakos (0082884) Rachel Hazelet (0097855)

THE PATTAKOS LAW FIRM LLC

101 Ghent Road Fairlawn, Ohio 44333

Phone: 330.836.8533 Fax: 330.836.8536 peter@pattakoslaw.com rhazelet@pattakoslaw.com

Joshua R. Cohen (0032368) Ellen Kramer (0055552)

COHEN ROSENTHAL & KRAMER LLP The Hoyt Block Building, Suite 400

Cleveland, Ohio 44113 Phone: 216.781.7956 Fax: 216.781.8061

jcohen@crklaw.com

Attorneys for Plaintiffs

Certificate of Service

The foregoing document was filed on May 15, 2019, using the Court's electronic-filing system, which will serve copies on all necessary parties.

/s/ Rachel Hazelet	
Attorney for Plaintiffs	



Sam N. Ghoubrial M.D., Inc. 1134 Brown Street, Suite A1 Akron, Ohio 44301 PHONE 330-331-7207 FAX 330-331-7567

May 23, 2012 Richie Harbour

Richie is a 31-year-old gentleman who was involved in a motor vehicle accident on May 10, 2012. He was the seat-belted driver of a vehicle that was sitting in traffic on Route 18 when his vehicle was rear-ended. As a result, he injured his lower back. On a scale of 1 to 10, his pain is 8 out of 10. He went to the emergency room at Akron General West where he was treated and released.

Past Medical History: 1. Cerebral palsy.

Social History: Unremarkable.

MEDICATIONS: Flexeril.

ALLERGIES: NKDA.

PHYSICAL EXAM:

INTEGUMENTARY: The skin is without any cyanosis. No evidence of nail fungus, rash or abnormality. Elasticity appears to be WNL.

HEENT: Normocephalic and atraumatic. PERRLA. Mucous membranes are moist. The nose is patent and non-deviated. Tympanic membranes WNL.

NECK: Soft and supple. Thyroid gland could not be palpated. No evidence of any cervical lymphadenopathy. No JVD is noted.

CARDIOVASCULAR: RRR normal S1 S2, no murmurs rubs or gallops. No carotid bruits could be appreciated.

LUNGS: Clear to auscultation. No wheezes, rales, or rhonchi could be appreciated on exam.

ABDOMEN: Soft and non-tender with positive bowel sounds. No evidence of any ascites or hepatosplenomegaly. No guarding or rebound tenderness. Negative for hernias.

GRASP/MANIPULATION: Pincer movements and fine coordination appear to be WNL.







Patient Name: Richie Harbour

Page Two

SPINE/BACK: No scars are present. He has guarding and tenderness of the lumbar spine with reproducible pain and tenderness to the cervical spine. He has significant decreased range of motion of the lumbar spine. He has some guarding and spasm of the cervical spine with decreased range of motion on flexion and extension.

UPPER EXTREMITIES: Shoulders, wrists and elbows: demonstrate no scars. +2 radial pulses throughout. He has some rigidity and decreased range of motion at the upper extremities bilaterally secondary to cerebral palsy. He has difficulty with fine manipulation of his hands.

LOWER EXTREMITIES: No venous insufficiency or edema. +2 pulses throughout. Ankles and hips demonstrate no gross abnormalities on exam. He has decreased range of motion of the lower extremities secondary to cerebral palsy. He has significant decreased range of motion at the hips and knees secondary to cerebral palsy with dystonia noted.

MUSCULOSKELETAL: The patient is unable to get on and off the exam table. The patient has an unsteady gait and walks with the aid of a walker. He has difficulty getting up from a seated position.

NEUROLOGICAL: The patient is alert and oriented x 3. Cranial nerves II-XII are grossly intact throughout. Reflexes are 2/4 throughout. Tactile sensation is WNL. There is a negative Romberg test. Cerebellar testing is within normal limits. There is a negative straight leg raise and negative bowstring sign.

ASSESSMENT:

- 1. Cerebral palsy.
- 2. Cervical strain.
- 3. Lumbar strain.

PLAN: I put him on Flexeril #30, one b.i.d.; Percocet 5/325 mg, #30, one b.i.d.; and Motrin 800 mg, #30, one b.i.d. I will see the patient back in two weeks.

SPECIAL NOTE: I provided the patient with a Lux TENS unit. I gave explicit instructions on how to use it.

Sam N. Ghoubrial M.D./rtd

CLIENT: Richard A Harbour

INSURANCE CO: Erie Insurance Group

INSURED: Thomas Fisher

ADJUSTER: Meg Wright

ATE OF LOSS: 5/10/2012

CLAIM NO: 010710323711

PHYSICIANS	MEDICAL SPECIALS	AMOUNT
Rolling Acres Chiropractic Inc Clearwater Billing Services, LLC	(5/21/2012 - 10/25/2012) (5/23/2012 - 6/20/2012)	\$ 3,887.00 \$ 2,110.00
HOSPITALS:		
Akron General Medical Center General Emergency Medical Specialists	(5/10/2012 - 5/10/2012) (5/10/2012 - 5/10/2012)	\$ 1,505.93 \$ 105.00
Radiology & Imaging Services	(5/10/2012 - 5/10/2012)	\$ 38.00
Akron General Medical Center General Emergency Medical Specialists	(6/27/2012 - 6/27/2012) (6/27/2012 - 6/27/2012)	\$ 3,141.62 \$ 199.00
Radiology & Imaging Services	(6/27/2012 - 6/27/2012)	\$ 143.00
OTHERS:		
Bath Fire Department	(5/10/2012 - 5/10/2012)	\$ 450.00
TOTAL MEDICAL SPECIALS:		\$ 11,579.55

KISLING, NESTICO & REDICK $\bar{3}\bar{4}\bar{1}2$ WEST MARKET STREET

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 08/05		Al	KRON, OH	44333	
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2. PATIENT'S NAME (Last Name, First Name, Middle Initial)	3. PATIENT'S BIRTH DATE	SEX	4. INSURED'S NAME	Last Name, First N	ame, Middle Initial)
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 PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE 1 authorize the to process this claim. I also request payment of government benefits either 	release of any medical or other information role of any medical or to the party who accepts ass	on necessary dgnment	payment of medical services described to	benefits to the unde	ersigned physician or supplier for
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to process this claim. I also request payment of government benefits eithe below.	r to myself or to the parly who a	accepts assignment	services describe	d below.			rice priyerenary or dappiner io
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Invoice for Medical Services

Re: Richie Harbour

Date of Accident: 5/10/12

Date of Birth:

Medical services for the above- named client. Amount

5/23/12—6/20/12

See detailed HCFA 1500

\$2110.00

8/3/12

Document preparation fee

\$50.00

Total amount due:

\$2160.00

Please make checks payable to:

Clearwater Billing Service, LLC P.O. Box 1243 Bath, Ohio 44210-1243

Tax ID: 27-0845852

PROGRESSIVE P.O. BOX 512926 LOS ANGELES, CA 90051

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512548 9352 1 MB 0.435 CMBPI012 043 009352

Recipient: CLEARWATER BILLING SERVICES P.O. BOX 1243 BATH, OH 44210

Patient: RICHIE HARBOUR



Underwritten By: PROGRESSIVE CASUALTY INSURANCE COMPANY

Document Date: August 18, 2014 Claim Number: 08-4720936 Date of Loss: June 9, 2008 Policyholder: HARBOUR, RICHIE State of Jurisdiction: OH

Coverage Type: MEDICAL PAYMENTS COVERAGE

Date Received: August 14, 2014 Bill Number: 33766508

Provider Invoice Number: HANCHRISTLLC Progressive Invoice Number: 14111012

Provider Information: CLEARWATER BILLING SERVICES P.O. BOX 1243 BATH, OH 44210

Specialty: GENERAL PRACTICE Zip of Service: 44301

Region: 442

Date(s) of Service: 05/23/2012 - 06/20/2012

Page 1 of 2

Explanation of Benefits

ICD Diagnosis Codes:

343.9

Infantile cerebral palsy, unspecified

847.0

Neck sprain

847.2

Lumbar sprain

ICD Procedure Codes:

Date of Service	Line	Revenue Code	Place of Service	Procedure Code	Modifier	Units	Amount Charged	Amount Allowed	Explanation Codes
05/23/2012	1		11	99204		1	\$350.00	\$0.00	9980
05/23/2012	2		11	E0730		1	\$500.00	\$0.00	9980
06/06/2012	3		11	99213		1	\$150.00	\$0.00	9980
06/20/2012	4		11	99213		1	\$150.00	\$0.00	9980
06/06/2012	5		11	20552		1	\$400.00	\$0.00	9980
06/06/2012	6		11	J1040		1	\$80.00	\$0.00	9980
06/20/2012	7		11	20552		1	\$400.00	\$0.00	9980
06/20/2012	8		11	J1040		1	\$80.00	\$0.00	9980
Subtotals							\$2,110.00	\$0.00	
Deductible/Co-Pay								\$0.00	
Totals							\$2,110.00	\$0.00	

Revenue Code:

Place of Service:

11 - Office

Procedure Code:



Rolling Acres Chiropractic Clinic Inc Shawn Auck

2537 Romig Rd Akron OH 44320 (330) 745-8300

October 30, 2012

Reddick, Kisling, Nestico 3412 W. Market Akron, OH 44333

Federal ID # 34-1935322

NFIL

Patient #: 5212 RE: Ritchie Harbour Insurance ID:

Diagnosis For Accident On 05/10/12 847.0 Cervical Sprain/Strain 784.0 Cephalgia

847.2 Lumbar Sprain/Strain

Date	Service Descriptions	Charge	Receipt Total
05/21/12	97010 Hot Pack; One Area	15.00	15.00
05/21/12	97012 INTERSEGMENTAL TRACTION	25.00	40.00
05/21/12	97014 LOW VOLT SINE THERAPY	25.00	65.00
05/22/12	98940 CMT; 1-2 Regions	38.00	103.00
05/22/12	97010 Hot Pack; One Area	15.00	118.00
05/22/12	97012 INTERSEGMENTAL TRACTION	25.00	143.00
05/22/12	97014 LOW VOLT SINE THERAPY	25.00	168.00
05/22/12	97124 massage	20.00	188.00
05/24/12	98940 CMT; 1-2 Regions	38.00	226.00
05/24/12	97010 Hot Pack; One Area	15.00	241.00
05/24/12	97012 INTERSEGMENTAL TRACTION	25.00	266.00
05/24/12	97014 LOW VOLT SINE THERAPY	25.00	291.00
05/24/12	97124 massage	20.00	311.00
05/29/12	98940 CMT; 1-2 Regions	38.00	349.00
05/29/12	97010 Hot Pack; One Area	15.00	364.00
05/29/12	97012 INTERSEGMENTAL TRACTION	25.00	389.00
05/29/12	97014 LOW VOLT SINE THERAPY	25.00	414.00
05/29/12	97124 massage	20.00	434.00
05/30/12	98940 CMT; 1-2 Regions	38.00	472.00
05/30/12	97010 Hot Pack; One Area	15.00	487.00
05/30/12	97012 INTERSEGMENTAL TRACTION	25.00	512.00
05/30/12	97014 LOW VOLT SINE THERAPY	25.00	537.00
05/30/12	97124 massage	20.00	557.00
06/04/12	98940 CMT; 1-2 Regions	38.00	595.00
06/04/12	97010 Hot Pack; One Area	15.00	610.00
06/04/12	97012 INTERSEGMENTAL TRACTION	25.00	635.00
06/04/12	97014 LOW VOLT SINE THERAPY	25.00	660.00
06/04/12	97124 massage	20.00	680.00
06/05/12	98940 CMT; 1-2 Regions	38.00	718.00
06/05/12	97010 Hot Pack; One Area	15.00	733.00
)6/05/12	97012 INTERSEGMENTAL TRACTION	25.00	758.00
06/05/12	97014 LOW VOLT SINE THERAPY	25.00	783.00
06/05/12	97124 massage	20.00	803.00
06/12/12	98940 CMT; 1-2 Regions	38.00	841.00
06/12/12	97010 Hot Pack; One Area	15.00	856.00
06/12/12	97012 INTERSEGMENTAL TRACTION	25.00	991.00
			KNR05038 661.00

RE: Ritchie Harbour

October 30, 2012

E: Kitchie Har	October 30, 201	2	
Date	Service Descriptions		D
06/12/12	97014 LOW VOLT SINE THERAPY	Charge	Receipt Total
06/12/12	97124 massage	25.00	906.00
06/14/12	98940 CMT; 1-2 Regions	20.00	926.00
06/14/12	97010 Hot Pack; One Area	38.00	964.00
06/14/12	97012 INTERSEGMENTAL TRACTION	15.00	979.00
06/14/12	97014 LOW VOLT SINE THERAPY	25.00	1004.00
06/14/12	97424 manage	25.00	1029.00
06/18/12	97124 massage	20.00	1049.00
	98940 CMT; 1-2 Regions	38.00	
06/18/12	97010 Hot Pack; One Area	15.00	1087.00
06/18/12	97012 INTERSEGMENTAL TRACTION	25.00	1102.00
06/18/12	97014 LOW VOLT SINE THERAPY	25.00	1127.00
06/18/12	97124 massage		1152.00
06/19/12	98940 CMT; 1-2 Regions		1172.00
06/19/12	97010 Hot Pack; One Area	38.00	1210.00
06/19/12	97012 INTERSEGMENTAL TRACTION	15.00	1225.00
06/19/12	97014 LOW VOLT SINE THERAPY	25.00	1250.00
06/19/12	97124 massage	25.00	1275.00
06/25/12	98940 CMT; 1-2 Regions	20.00	1295.00
06/25/12	97010 Hot Pack; One Area	38.00	1333.00
06/25/12	07040 INTERCEOMENTAL TRACTION	15.00	1348.00
	97012 INTERSEGMENTAL TRACTION	25.00	1373.00
06/25/12	97014 LOW VOLT SINE THERAPY	25.00	1398.00
06/25/12	97124 massage	20.00	1418.00
06/26/12	98940 CMT; 1-2 Regions	38.00	
06/26/12	97010 Hot Pack; One Area	15.00	1456.00
06/26/12	97012 INTERSEGMENTAL TRACTION	25.00	1471.00
06/26/12	97014 LOW VOLT SINE THERAPY	25.00	1496.00
06/26/12	97124 massage		1521.00
06/28/12	98940 CMT; 1-2 Regions	20.00	1541.00
06/28/12	97010 Hot Pack; One Area	38.00	1579.00
06/28/12	97012 INTERSEGMENTAL TRACTION	15.00	1594.00
06/28/12	97014 LOW VOLT SINE THERAPY	25.00	1619.00
06/28/12	97124 massage	25.00	1644.00
07/02/12	98940 CMT; 1-2 Regions	20.00	1664.00
07/02/12	97010 Hot Pack; One Area	38.00	1702.00
07/02/12	97014 LOW/VOLT CINE TUEDARY	15.00	1717.00
	97014 LOW VOLT SINE THERAPY	25.00	1742.00
07/02/12	97124 massage	20.00	1762.00
07/05/12	98940 CMT; 1-2 Regions	38.00	1800.00
07/05/12	97010 Hot Pack; One Area	15.00	1815.00
07/05/12	97012 INTERSEGMENTAL TRACTION	25.00	1840.00
07/05/12	97014 LOW VOLT SINE THERAPY	25.00	1865.00
07/05/12	97124 massage	20.00	1885.00
07/09/12	98940 CMT; 1-2 Regions	38.00	
07/09/12	97010 Hot Pack; One Area	15.00	1923.00
07/09/12	97012 INTERSEGMENTAL TRACTION		1938.00
07/09/12	97014 LOW VOLT SINE THERAPY	25.00	1963.00
07/09/12	97124 massage	25.00	1988.00
07/12/12	98940 CMT; 1-2 Regions	20.00	2008.00
07/12/12	97010 Hot Pack; One Area	38.00	2046.00
07/12/12	97014 LOW VOLT SINE THERAPY	15.00	2061.00
07/12/12		25.00	2086.00
07/16/12	97124 massage	20.00	2106.00
	98940 CMT; 1-2 Regions	38.00	2144.00
07/16/12	97010 Hot Pack; One Area	15.00	2159.00
07/16/12	97012 INTERSEGMENTAL TRACTION	25.00	2184.00
07/16/12	97014 LOW VOLT SINE THERAPY	25.00	2209.00
07/17/12	98940 CMT; 1-2 Regions	38.00	2247.00
07/17/12	97010 Hot Pack; One Area	15.00	2262.00
07/17/12	97012 INTERSEGMENTAL TRACTION	25.00	
07/17/12	97014 LOW VOLT SINE THERAPY	25.00	2287.00
07/19/12	98940 CMT; 1-2 Regions	38.00	2312.00
07/19/12	97010 Hot Pack; One Area		2350.00
07/19/12	97012 INTERSEGMENTAL TRACTION	15.00	2365.00
07/19/12	97014 LOW VOLT SINE THERAPY	25.00	2390.00
07/23/12		25.00	2415.00
	98940 CMT; 1-2 Regions	38.00	2453.00
07/23/12	97010 Hot Pack; One Area	15.00	2468.00
07/23/12	97012 INTERSEGMENTAL TRACTION	ر 25.00	NR05039 ^{2493.00}
		K	NKU5U39

NFIL

RE: Ritchie Harbour October 30, 2012 Date Service Descriptions Charge Receipt Total 07/23/12 97014 LOW VOLT SINE THERAPY 25.00 2518.00 07/24/12 98940 CMT; 1-2 Regions 38.00 2556.00 07/24/12 97010 Hot Pack; One Area 15.00 07/24/12 2571.00 97012 INTERSEGMENTAL TRACTION 25.00 07/24/12 2596.00 97014 LOW VOLT SINE THERAPY 25.00 07/27/12 2621.00 98940 CMT; 1-2 Regions 38.00 07/27/12 2659.00 97010 Hot Pack; One Area 15.00 07/27/12 2674.00 97012 INTERSEGMENTAL TRACTION 25.00 07/27/12 2699.00 97014 LOW VOLT SINE THERAPY 25.00 07/31/12 2724.00 98940 CMT; 1-2 Regions 38.00 2762.00 07/31/12 97010 Hot Pack; One Area 15.00 07/31/12 2777.00 97012 INTERSEGMENTAL TRACTION 25.00 97014 LOW VOLT SINE THERAPY 2802.00 07/31/12 25.00 2827.00 08/02/12 98940 CMT; 1-2 Regions 38.00 2865.00 08/02/12 97010 Hot Pack; One Area 15.00 2880.00 08/02/12 97012 INTERSEGMENTAL TRACTION 25.00 2905.00 08/02/12 97014 LOW VOLT SINE THERAPY 25.00 2930.00 08/06/12 98940 CMT; 1-2 Regions 38.00 2968.00 08/06/12 97010 Hot Pack; One Area 15.00 2983.00 97012 INTERSEGMENTAL TRACTION 08/06/12 25.00 3008.00 08/06/12 97014 LOW VOLT SINE THERAPY 25.00 3033.00 08/07/12 98940 CMT; 1-2 Regions 38.00 3071.00 08/07/12 97010 Hot Pack; One Area 15.00 08/07/12 3086.00 97012 INTERSEGMENTAL TRACTION 25.00 3111.00 97014 LOW VOLT SINE THERAPY 08/07/12 25.00 3136.00 98940 CMT; 1-2 Regions 08/13/12 38.00 3174.00 08/13/12 97010 Hot Pack; One Area 15.00 3189.00 08/13/12 97012 INTERSEGMENTAL TRACTION 25.00 3214.00 97014 LOW VOLT SINE THERAPY 08/13/12 25.00 3239.00 98940 CMT; 1-2 Regions 08/14/12 38.00 3277.00 98940 CMT; 1-2 Regions 08/16/12 38.00 3315.00 08/20/12 98940 CMT; 1-2 Regions 38.00 3353.00 08/21/12 98940 CMT; 1-2 Regions 38.00 3391.00 08/23/12 98940 CMT; 1-2 Regions 38.00 3429.00 08/27/12 98940 CMT; 1-2 Regions 38.00 3467.00 08/30/12 98940 CMT; 1-2 Regions 38.00 3505.00 09/04/12 98940 CMT; 1-2 Regions 38.00 3543.00 09/07/12 98940 CMT; 1-2 Regions 38.00 3581.00 09/13/12 98940 CMT; 1-2 Regions 38.00 3619.00 09/20/12 98940 CMT; 1-2 Regions 38.00 3657.00 09/27/12 98940 CMT; 1-2 Regions 38.00 3695.00 10/04/12 98940 CMT; 1-2 Regions 38.00 3733.00 10/09/12 98940 CMT; 1-2 Regions 38.00 3771.00 10/18/12 98940 CMT; 1-2 Regions 38.00 3809.00 10/25/12 98940 CMT; 1-2 Regions 38.00 3847.00 10/25/12 9921225 EXAM FOCUSED

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05/15/2019 20:51:50 PM

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Page 14 of 201

7/1/2015 03:37 PM

Page 1 of 3

221620 / Harbour, Mr. Richard

Settlement Memorandum

Recovery:

REC

MP Progressive Insurance* \$ 5,000.00

Eriè Insurance

\$ 17,500.00

\$ 22,500.00

DEDUCT AND RETAIN TO PAY:

Kisling Legal Group

Akron General Health System*;	\$ 2.50
AMC Investigations;	\$ 40.00
Clearwater Billing Services, LLC;	\$ 50.00
First Healthcare**; dd	\$ 12.00
HealthPort; dd	\$ 48.23
Kisling, Nestico & Redick, LLC; Filing Fee/rjk	\$ 386.25
Professional Receivables Control, Inc.*;	\$ 16.00
Trisha Beban Yost, RPR; #6018/depo of Fischer	\$ 55.00
Insha began fost, KPK, #60 to/depo of tischer	\$ 50.00

Total due Kisling Legal Group

\$ 609.98

DEDUCT AND RETAIN TO PAY TO OTHERS:

Bath Fire Department	\$ 450.00
Clearwater Billing Services, LLC	\$ 2.110:00 1900 .00
Kisling, Nestico & Redick, LLC	\$ 6,388.33
Progressive Insurance*	\$ 3,335.00
Radiology & Imaging Services	\$ 85.01
Rolling Acres Chiropractic Inc	\$3. 887.00 3,3 3 1.69

Total due Others

\$ 16,255.34

Total Deductions

Total Amount Due To Client

Less Previously Paid To Client

Net Amount Due Client

\$ 16,865.32

\$5,634.68

\$ 0.00

6400 · S 5,634.68

I hereby approve the above settlement and distribution of proceeds. I have reviewed the above information and I acknowledge that it accurately reflects all outstanding expenses associated with my injury claim. I further understand that the itemized bills listed above will be deducted and paid from the gross amount of my settlement except as otherwise indicated. Finally, I understand that any bills not listed above, including but not limited to Health Insurance or Medical Payments Subrogation and/or those initialed by me to indicate that they are not being paid from the settlement are my responsibility and not the responsibility of Kisling, Nestico & Redick, LLC.

Former Clunt

Date:	Name:	
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	Tubran	
	d in R.D	
	9 NO P. J.	

KNR05341

7/27/2015

221620 / Richard Harbour

Settlement Memorandum

Recovery:

MP	Progressive Insurance*	\$ 5,000.00
REC	Erie Insurance	<u>\$ 17,500.00</u>
		\$ 22 500 00

DEDUCT AND RETAIN TO PAY:

Kisling, Nestico & Redick, LLC	
AMC Investigations;	\$ 40.00
Clearwater Billing Services, LLC;	\$ 50.00
First Healthcare**; dd	\$ 12.00
HealthPort; dd	\$ 48.23
Kisling, Nestico & Redick, LLC; Filing Fee/rjk	\$ 386.25
Professional Receivables Control, Inc.*;	\$ 16.00
Trisha Beban Yost, RPR; #6018/depo of Fischer	\$ 55.00
Akron General Health System*;	<u>\$ 2.50</u>
Total Due	\$ 609.98

DEDUCT AND RETAIN TO PAY TO OTHERS:

Bath Fire Department	\$ 450.00
Clearwater Billing Services, LLC	\$ 1,900.00
Kisling, Nestico & Redick, LLC	\$ 6,388.33
Progressive Insurance*	\$ 3,335.00
Radiology & Imaging Services	\$ 38.00
Radiology & Imaging Services	\$ 47.01
Rolling Acres Chiropractic Inc	<u>\$ 3,331.68</u>
Total Due Others	\$ 15.490.02

Net Amount Due to Client	\$ 6,400.00
Less Previously Paid to Client	\$ 0.00
Total Amount Due to Client	\$ 6,400.00
Total Deductions	\$ 16,100.00

I hereby approve the above settlement and distribution of proceeds. I have reviewed the above information and I acknowledge that it accurately reflects all outstanding expenses associated with my injury claim. I further understand that the itemized bills listed above will be deducted and paid from the gross amount of my settlement except as otherwise indicated. Finally, I understand that any bills not listed above, including but not limited to Health Insurance or Medical Payments Subrogation and/or those initialed by me to indicate that they are not being paid from the settlement are my responsibility and not the responsibility of Kisling, Nestico & Redick, LLC.

Date:	Name:	
		Richard Harbour
	Firm:	
		Kisling, Nestico & Redick, LLC

NFIL

7/27/2015

221620 / Richard Harbour

Settlement Memorandum

R	8	CC	V	e	ľ	Y	:

MP	Progressive Insurance*	\$ 5,000.00
REC	Erie Insurance	<u>\$ 17,500.00</u>
		\$ 22.500.00

DEDUCT AND RETAIN TO PAY:

Kisling, Nestico & Redick, LLC	
AMC Investigations;	\$ 40.00
Clearwater Billing Services, LLC;	\$ 50.00
First Healthcare**; dd	\$ 12.00
HealthPort; dd	\$ 48.23
Kisling, Nestico & Redick, LLC; Filing Fee/rjk	\$ 386.25
Professional Receivables Control, Inc.*;	\$ 16.00
Trisha Beban Yost, RPR; #6018/depo of Fischer	\$ 55.00
Akron General Health System*;	<u>\$ 2.50</u>
Total Due	\$ 609.98

DEDUCT AND RETAIN TO PAY TO OTHERS:

Bath Fire Department	\$ 450.00
Clearwater Billing Services, LLC	\$ 1,900.00
Kisling, Nestico & Redick, LLC	\$ 6,388.33
Progressive Insurance*	\$ 3,335.00
Radiology & Imaging Services	\$ 38.00
Radiology & Imaging Services	\$ 47.01
Rolling Acres Chiropractic Inc	<u>\$ 3,331.68</u>
Total Due Others	\$ 15,490.02

Total Deductions	\$ 16,100.00
Total Amount Due to Client	\$ 6,400.00
Less Previously Paid to Client	\$ 0.00
Net Amount Due to Client	\$ 6,400.00

NFIL

I hereby approve the above settlement and distribution of proceeds. I have reviewed the above information and I acknowledge that it accurately reflects all outstanding expenses associated with my injury claim. I further understand that the itemized bills listed above will be deducted and paid from the gross amount of my settlement except as otherwise indicated. Finally, I understand that any bills not listed above, including but not limited to Health Insurance or Medical Payments Subrogation and/or those initialed by me to indicate that they are not being paid from the settlement are my responsibility and not the responsibility of Kisling, Nestico & Redick, LLC.

Date:

Name:

Richard Harbo

Firm:

KNR05023

CLIENT: Thera Reid

INSURANCE CO: Allstate Insurance Companies

DEFENDANT: Donnie Portis

ADJUSTER: Jessica Oskins

DATE OF LOSS: 4/20/2016

TOTAL MEDICAL SPECIALS:

CLAIM NO: 0410714125

HOSPITALS:	MEDICAL SPECIALS	AMOUNT
Summa Health System Summa Emergency Associates, Inc. Akron Radiology American Medical Response	(4/20/2016 - 4/21/2016) (4/20/2016) (4/20/2016 - 4/21/2016) (4/20/2016)	\$ 33,126.50 \$ 675.00 \$ 1,045.00 \$ 1,110.57
PHYSICIANS: SPI Surgical Specialties Akron Square Chiropractic Clearwater Billing Services, LLC North Star Orthopedic Group National Diagnostic Imaging	(4/21/2016 - 5/10/2016) (4/22/2016 - 7/12/2016) (4/27/2016 - 6/1/2016) (6/9/2016 - 6/9/2016) (6/7/2016 - 6/7/2016)	\$ 505.00 \$ 5,025.00 \$ 3,460.00 \$ 164.00 \$ 200.00



\$ 45,311.07

Sam N. Ghoubrial M.D. PHONE 330-331-7207 FAX 330-331-7567

April 27, 2016 Thera Reid

Thera is a 37-year-old very pleasant woman who had a motorcycle accident on April 20, 2016. She was the passenger on the back of a motorcycle when the motorcycle approached an intersection and a SUV ran a stop sign. The motorcycle driver slammed on the brakes and Thera went flying off the back of the motorcycle and broke her right humerus. She went to the emergency room at Akron City Hospital by ambulance where she was treated and released. She is unfortunately in severe pain in her shoulder, neck, and back. On a scale of 1 to 10, her pain is 10 out of 10 in severity. She has significant pain and discomfort. She is going to be seeing the orthopedic surgeon.

Past Medical History: 1. Nystagmus. 2. Migraines. 3. Hypothyroidism.

Past Surgical History: 1. C-section x 2. 2. Hysterectomy. 3. Thyroidectomy. 4. Retinal detachment.

Social History: No history of illicit drug use. Positive for tobacco use.

MEDICATIONS: Oxycodone from the emergency room. She notes that it did not help. Sumatriptan, propranolol, Paxil, levothyroxine.

ALLERGIES: NKDA.

PHYSICAL EXAM:

HEENT: Normocephalic and atraumatic. PERRLA. Mucous membranes are moist. The nose is patent and non-deviated.

NECK: Thyroid gland could not be palpated. No evidence of any cervical lymphadenopathy. No JVD is noted.

SPINE/BACK: No scars are present. She has severe pain and tenderness at the cervical and upper thoracic spine. She has reproducible pain and discomfort, guarding and spasms. She has significant tenderness of the lumbar spine, left greater than right, with loss of lordosis.

GRASP/MANIPULATION: Pincer movements and fine coordination appear to be WNL.

UPPER EXTREMITIES: Her right upper extremity is immobilized. She has a 40×60 cm bruise in the right biceps and right upper shoulder region. She has severe pain on palpation in that area. She has no range of motion of the right shoulder. The right upper extremity is in a sling.

Patient Name: Thera Reid

Page Two

LOWER EXTREMITIES: No venous insufficiency or edema. +2 pulses throughout. Ankles and hips demonstrate no gross abnormalities on exam.

MUSCULOSKELETAL: The patient is able to get on and off the exam table without difficulty. The patient is able to do heel to toe walking. The patient doesn't walk with a cane or walker.

NEUROLOGICAL: The patient is alert and oriented x 3. Cranial nerves II-XII are grossly intact throughout. Reflexes are 2/4 throughout. Tactile sensation is WNL. There is a negative Romberg test. Cerebellar testing is within normal limits. There is a negative straight leg raise and negative bowstring sign.

ASSESSMENT:

- 1. Cervical strain.
- 2. Thoracic sprain.
- 3. Lumbar strain.

PROCEDURE:

- 1. I identified four trigger points, one at L1, L2, L3, L4, left side. I introduced a total of 1 cc methylprednisolone and 3 cc of Marcaine.
- 2. I identified four trigger points, one at C7, T1, T2, T3, right side. I introduced a total of 1 cc methylprednisolone and 3 cc of Marcaine.

PLAN: I prescribed Percocet 5/325 mg, #21, one pill t.i.d.; and Zanaflex 4 mg, #30, one at night.

I want the patient to continue therapy. The patient understands he/she needs to participate in therapy, and is actively participating in therapy.

Su poddo

Sam N. Ghoubrial M.D./rtd

Progress Notes

Name	IMM RUU	
4.7114	8 Frank Raid	
	Initial Visit. (AIS)	
5/4/10 7	7 Thera Reial	
	FOILOW UP ONS	
		
	Thera Reid May 4, 2016	
r	The patient is here for a follow-up visit. Her arm is still in a sling. She said she had tremendous relief after the trigger point injections in her lower back.	
F	EXAM: The patient still has some discomfort in her neck on the right side. She still has guarding and tenderness in the right trapezius complex. She has cervical tenderness and pain.	
F	PROCEDURE: I identified four trigger points, one at C3, C4, C5, C6, right side. I introduced a	
F	total of 1 cc methylprednisolone and 3 cc of Marcaine. PLAN: I will refer her to Dr. Chonko. I refilled Percocet 5/325 mg, #40, one t.i.d. as needed.	
S	SNG/rtd See The See Th	
-1 1119	9 Thosa Rud	
	MIDW UP. (NS)	
	era Reid May 18, 2016	
	e patient is here for a follow-up visit. She is scheduled to see Dr. Chonko/Ortho. She said the rcocet has been helpful.	
EX.	KAM: The patient's right arm is still immobilized. She has swelling from the fracture. The rvical region is still uncomfortable.	,
PL	AN: I agreed to give her 50 Percocet 5/325 mg, one t.i.d.	
SN	VG/rtd	
= 1 1		
2/ 1U S	SPht referred to Dr. Chonko. Called pt and)
	gave them into to schedul. and	
<u>l</u>		

Name:	Thera Rejd
52511u	2 Shera Reid Follow UP- DE
	Thera Reid May 25, 2016 The patient is here for a follow-up visit. Thera is going to have extensive surgery on her right arm for the fracture to the shoulder. EXAM: She has swelling of her right arm and is still in a sling. She has severely limited range of motion to her right upper extremity. She has significant guarding and spasm of the cervical and upper thoracic spine. PROCEDURE: I identified four trigger points, two at C7 and two at T1. I introduced a total of 1 cc methylprednisolone and 3 cc of Marcaine. PLAN: I will refer her to Chronic Pain Management. Dr. Chonko is going to do surgery. SNG/rtd
6/1/14	1 Thera Reid FOILOW up (NS)
·	Thera Reid June 1, 2016 The patient is here for a follow-up visit. She is going to have surgery of her shoulder. The trigger point injections were very beneficial to her neck. PLAN: I refilled Percocet 5/325 mg, #60, one PO t.i.d. as needed with no refills. SNG/rtd
·	



HEALTH INSURANCE CLAIM FORM

THERA REID

APPROVED BY NATIONAL UNIFORM CLAIM PICA	COMMITTEE (NUCC) 02/12									PICA I
1. MEDICARE MEDICAID TRIC	CARE	CHAMPVA	GROU	P FECA	OTHER	R 1a. INSURED	S LD. N	UMBER	White currents	СТАСНОНИКОВОЮ	(For Program in Item 1)
(Medicare#) (Medicaid#) (ID#/	(DoD#) [(Member ID:	r) (ID#)	H PLAN BLK LU	NG X (ID#)						(For Fragram in nem 1)
2. PATIENT'S NAME (Last Name, First Name,	Middle Initial)		3. PATIENT'S	BIRTH DATE	SEX	4. INSURED'S	NAME	(Last Na	me, Firs	t Name	e, Middle Initial)
REID, THERA				M	FX	REID,					
5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RE	ELATIONSHIP TO IN	SURED	7. INSURED'S			, Street)	1	**:	
			Self X S	pouse Child	Other						
CITY		STATE	8. RESERVED	FOR NUCC USE		CITY	_				STATE
ZIP CODE TELEPHON	IE (Include Are	a Code)				ZIP CODE	2000		TEL	EPHO	NE (Include Area Code)
9. OTHER INSURED'S NAME (Last Name, First	st Name, Middle	e initial)	10. IS PATIENT	'S CONDITION RELA	ATED TO:	11, INSURED'S	S POLIC	CY GROU	JP OR F	ECA N	UMBER
OT ITS WOULD BE A STATE OF THE	****										
a. OTHER INSURED'S POLICY OR GROUP N	UMBER	1	a. EMPLOYME	NT? (Current or Previ		a. INSURED'S	DATE	OF BIRTH	Н		SEX
b. RESERVED FOR NUCC USE				YES XNO)					, N	Λ FX
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C. RESERVED FOR NOCE USE		1	OTHER ACC	7 5		c. INSURANCE			R PROG	SRAM	NAME
d. INSURANCE PLAN NAME OR PROGRAM N	11110		L	YES - NO		THERA I					
G. INSUNANCE PEAN NAME OF PROGRAM N	VAIVIE	1	iod. CLAIM CO	DES (Designated by	NUCC)	d. IS THERE A	A. Same	R HEALT	TH BENE	EFIT P	LAN?
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to process this claim. I also request payment of below.	of government t	enefits either to	myself or to the	party who accepts as	signment	services des	cribed	below.	10 1110 12	, returned	area physician or supplier for
SIGNATURE ON	FILE		DATE	06 16 20	116		SIG	NATU	IRE	ON	FILE
TE OF CURRENT ILLNESS, INJURY, or	PREGNANCY	(LMP) 15. OT	HER DATE	MI ANYMATINANAN INGKAMPANYANA	TANKEN KITS AND MILESTON (AZ	SIGNED_	TENT I	NATI E	EXAMPLE OF THE	minocianosa No 151 C	Jakon prominera de la companya del companya del companya de la com
04 20 16 QUAL 43		QUAL	1439	MØ 4 2001	18	FROM	I DE	NABLE A	Y WOH		CURRENT OCCUPATION MM DD YY
17. NAME OF REFERRING PROVIDER OR OT	HER SOURCE	17a.			en e		ATION	DATES	RELATE	TO ED TO	CURRENT SERVICES
		17b.	NPI		SEEDINE STATE	FROM	DE	, , ,	Y	TO	MM DD YYY
19. ADDITIONAL CLAIM INFORMATION (Design	gnated by NUC	C)				20. OUTSIDE L	AB?				HARGES
						YES	X	NO		*	0.00
21. DIAGNOSIS OR NATURE OF ILLNESS OR						22. RESUBMISS	Townson, J				
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24. A. DATE(S) OF SERVICE	B. G.	D. PROCEDI		ES, OR SUPPLIES] E.	F,	1	G	H.	1.	J.
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(I certify that the statements on the reverse apply to this bill and are made a part thereof.		S ARLIN			ļ	P.O BOX			and the file of		were a companie
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oco instruction Manual available al	i. www.nuc	c.org	PLEA!	SE PRINT OR T	YPE	AF	PPRO	VED C	MB-09	938-1	197 FORM 1500 (02-12)



THERA REID **HEALTH INSURANCE CLAIM FORM**

MEDICARE MEDICAID TRICARE CHAMP	HEALTH PLAN - B	ECA OTHER	R 1a. INSURED'S I.D. I	NUMBER	CHAO CHARACTURESCO	(For Program in Item 1)
(Medicare#) (Medicaid#) (ID#/DoD#) (Member	(ID#) $(ID#)$	D#)				
PATIENT'S NAME (Last Name, First Name, Middle Initial)	3. PATIENT'S BIRTH DATE	SEX	4. INSURED'S NAME		e, First Nam	ne, Middle Initial)
REID, THERA PATIENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP	M F X TO INSURED	REID, THE		(front)	
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STATE	8. RESERVED FOR NUCC US	hand beaut	10111			LOTANA LOTANA
OH						
TELEPHONE (Include Area Code)			ZIP CODE		TELEPHO	NE (Include Area Code)
OTHER INDUSTRIC NAME I					era e	
OTHER INSURED'S NAME (Last	10. IS PATIENT'S CONDITION	RELATED TO:	11. INSURED'S POLI	CY GROUP	OR FECA	NUMBER
OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or	Previous)	a. INSURED'S DATE	OF DIDTI		
	TTYES T	ONK	a. INSONED S DATE	OF BIRTH		SEX M□ E€□
RESERVED FOR NUCC USE	b. AUTO ACCIDENT?	PLACE (State)	b. OTHER CLAIM ID	(Designated	by NUCC)	<u>"LJ 'Ł]</u>
	XYES	NO OH		9,1410	ny modej.	
RESERVED FOR NUCC USE	c. OTHER ACCIDENT?		c. INSURANCE PLAN	NAME OR I	PROGRAM	NAME
INCUDANCE DI AN MAME CO COCCO	YES [NO	THERA REI			
INSURANCE PLAN NAME OR PROGRAM NAME	10d. CLAIM CODES (Designate	ed by NUCC)	d. IS THERE ANOTHE	I manufacture and the second	BENEFIT F	PLAN?
READ BACK OF FORM BEFORE COMPLETIN	IG & SIGNING THE FORM		hapayal Lamp	•		tete items 9, 9a, and 9d.
PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the to process this claim. I also request payment of government benefits either helow.	release of any medical or other let	ormation necessary pts assignment	13. INSURED'S OR At payment of medica services described	d benefits to	PERSON'S	S SIGNATURE I authorize igned physician or supplier for
SIGNATURE ON FILE TATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) 15.	DATE 06 16	2016	SIGNED	NATUR	220074577	
	JAL: 439 MM 4 DE	20 18	16. DATES PATIENT I	NABLE TO	WORK IN	CURRENT OCCUPATION MM DD YY
NAME OF REFERRING PROVIDER OR OTHER SOURCE 176			18. HOSPITALIZATION MM DE FROM	DATES RE		CURRENT SERVICES
ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		****	20. OUTSIDE LAB?	_i	T(CHARGES
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Akron Square Chiropractic 1419 South Arlington Rd. Akron, OH 44306 330-773-3882 ID#: 31-1528200

Minas Floros DC NPI#: 1306928650 Thursday July 14, 2016

Patient

: THERA REID

Itemized Statement: - 07/14/2016

DOB

Onset date

: 04/20/2016

Mail to: THERA REID

Insured

Insurance Carrier (primary)

DOB: Policy#:

Attorney

KISLING, NESTICO, AND REDICK 3412 W. MARKET ST AKRON OH 44333

Current Diagnosis

\$13.4XXA Sprain of ligaments of cervical spine, initial encounte

R51 Headache (facial pain NOS) S23.3XXA Sprain of ligaments of thoracic spine, initial encounte \$33.5XXA Sprain of ligaments of lumbar spine, initial encounter

M62.830 Muscle spasm of back

Thank you for your payment.

Employer

04/22/16 72040 X-RAY, SPINE, CERVICAL; 2 OR 3 VIEWS \$ 120.00 04/22/16 97014 ELECTRIC STIMULATION THERAPY \$ 45.00 04/22/16 97010 APPLICATION, AREAS; HOT/COLD PACKS \$ 30.00 04/25/16 9840 (CMT); SPINAL, 1-2 REGIONS \$ 85.00 04/27/16 97010 APPLICATION, AREAS; HOT/COLD PACKS \$ 30.00 04/27/16 97010 APPLICATION, AREAS; HOT/COLD PACKS \$ 30.00 04/27/16 97010 APPLICATION, AREAS; HOT/COLD PACKS \$ 30.00 04/27/16 97124 52 THERAPEUTIC PROC, EACH 15 MIN \$ 55.00 05/03/16 97014 ELECTRIC STIMULATION THERAPY \$ 45.00 05/03/16 97014 ELECTRIC STIMULATION THERAPY \$ 45.00 05/03/16 97014 ELECTRIC STIMULATION THERAPY \$ 45.00 05/03/16 97124 52 THERAPEUTIC PROC, EACH 15 MIN \$ 55.00 05/03/16 97124 52 THERAPEUTIC PROC, EACH 15 MIN \$ 55.00 05/03/16 97124 52 THERAPEUTIC PROC, EACH 15 MIN \$ 55.00 05/04/16 97014 ELECTRIC STIMULATION THERAPY \$ 45.00 05/04/16 97014 ELECTRIC STIMULATION THERAPY \$ 45.00 05/04/16 97010 APPLICATION, AREAS; HOT/COLD PACKS \$ 30.00 05/04/16 97010 APPLICATION, AREAS; HOT/COLD PACKS \$ 30.00 05/04/16 97010 APPLICATION, AREAS; HOT/COLD PACKS \$ 30.00 05/05/16 97014 ELECTRIC STIMULATION THERAPY \$ 45.00 05/09/16 97014 ELECTRIC STIMULATION THERAPY \$ 45.00 05/09/16 97014 ELECTRIC STIMULATION THERAPY \$ 55.00 05/09/16 97014 ELECTRIC STIMULATION THER	Date	Description		Amount:	***************************************
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	05/11/16	97010 APPLICATION, AREAS; HOT/COLD PACKS	Š	30.00	

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ate	98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 97010 APPLICATION, AREAS; HOT/COLD PACKS 98940 (CMT); SPINAL, 1-2 REGIONS 97124 52 THERAPEUTIC PROC, EACH 15 MIN 97014 ELECTRIC STIMULATION THERAPY 98940 (CMT); SP	Amount	
5/11/16	98940 (CMT); SPINAL, 1-2 REGIONS	\$ 85.00	
5/11/16	97124 52 THERAPEUTIC PROC, EACH 15 MIN	\$ 55.00	
5/13/16	97014 ELECTRIC STIMULATION THERAPY	\$ 45.00	
5/13/16	97010 APPLICATION, AREAS; HOT/COLD PACKS	\$ 30.00	
5/13/16	98940 (CMT); SPINAL, 1-2 REGIONS	\$ 85.00	
5/13/16	97124 52 THERAPEUTIC PROC, EACH 15 MIN	\$ 55.00	
5/16/16	97014 ELECTRIC STIMULATION THERAPY	ş 45.00	
5/16/16	97010 APPLICATION, AREAS; HOT/COLD PACKS	\$ 30.00	
5/16/16	98940 (CMT); SPINAL, 1-2 REGIONS	\$ 85.00	
5/16/16	97124 52 THERAPEUTIC PROC, EACH 15 MIN	\$ 55.00	
5/18/16	9/014 ELECTRIC STIMULATION THERAPY	\$ 45.00	
5/18/16	97010 APPLICATION, AREAS; HOT/COLD PACKS	\$ 30.00	
5/18/16	98940 (CMT); SPINAL, 1-2 REGIONS	\$ 85.00	
5/18/16	9/124 52 THERAPEUTIC PROC, EACH 15 MIN	\$ 55.00	
5/19/16	97014 ELECTRIC STIMULATION THERAPY	\$ 45.00	
5/19/16	97010 APPLICATION, AREAS; HOT/COLD PACKS	\$ 30.00	
5/19/16	98940 (CMI); SPINAL, 1-2 REGIONS	\$ 85.00	
2/13/10	97124 52 INEXAFEUTIC PROC, EACH 15 MIN	\$ 55.00	
5/23/16	97014 ELECTRIC STIMULATION THERREY	\$ 45.00	
2/23/16	97010 APPELCATION, AREAS; HOT/COLD PACKS	\$ 30.00	
5/23/16	90940 (CMI); SFINAL, I-2 REGIONS	\$ 85.00	
5/25/16	97124 92 INEKARBULLO FROC, EACH 19 MIN	\$ 55.00	
5/25/16	97014 EBECTRIC SIMULATION INEXAPI	\$ 45.00	
5/25/16	97010 AFFICATION, AREAS, BUILCOLD FACES	\$ 30.00	
5/25/16	90940 (CMI), SELWAD, I-2 REGIONS 07124 S2 THERRED DEUTE DOOC FROM 15 MIN	\$ 85.00	
5/23/10	97124 32 INERAFEUTIC FROC, EACH IS MIN	\$ 55.00	
5/31/16	97019 EDECIRIC SITUATION INEXAFT	\$ 45.00	••
5/31/16	90010 (FELCATION, AREAS, NOT/COLD FACES	\$ 30.00 \$ 85.00	
5/31/16	97124 52 THERAPEUTIC PROCEDED IS MIN	\$ 85.00 \$ 55.00	
6/01/16	97014 ELECTRIC STIMULATION THERAPY	\$ 55.00 \$ 45.00	
6/01/16	97010 APPLICATION. AREAS: HOT/COLD PACKS	\$ 30.00	
6/01/16	98940 (CMT): SPINAL. 1-2 REGIONS	\$ 85.00	
6/01/16	97124 52 THERAPEUTIC PROC. EACH 15 MIN	\$ 55.00	
6/06/16	97014 ELECTRIC STIMULATION THERAPY	\$ 45.00	
6/06/16	97010 APPLICATION, AREAS; HOT/COLD PACKS	\$ 30.00	
6/06/16	98940 (CMT); SPINAL, 1-2 REGIONS	\$ 85.00	
6/06/16	97124 52 THERAPEUTIC PROC, EACH 15 MIN	\$ 55.00	
6/07/16	97014 ELECTRIC STIMULATION THERAPY	\$ 45.00	
6/07/16	98940 (CMT); SPINAL, 1-2 REGIONS	\$ 85.00	
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6/10/16	97014 ELECTRIC STIMULATION THERAPY	\$ 45.00	
6/10/16	98940 (CMT); SPINAL, 1-2 REGIONS	\$ 85.00	
6/10/16	97039 UNLISTED MODALITY (SPECIFY TYPE & TIME)	\$ 50.00	
6/13/16	97014 ELECTRIC STIMULATION THERAPY	\$ 45.00	
6/13/16	98940 (CMT); SPINAL, 1-2 REGIONS	\$ 85.00	
6/13/16	97039 UNLISTED MODALITY (SPECIFY TYPE & TIME)	\$ 50.00	
6/17/16	97014 ELECTRIC STIMULATION THERAPY	\$ 45.00	
6/17/16	98940 (CMT); SPINAL, 1-2 REGIONS	\$ 85.00	
6/17/16	97039 UNLISTED MODALITY (SPECIFY TYPE & TIME)	\$ 50.00	
6/20/16	97014 ELECTRIC STIMULATION THERAPY	\$ 45.00	
6/20/16	98940 (CMT); SPINAL, 1-2 REGIONS	\$ 85.00	
6/27/16	97014 ELECTRIC STIMULATION THERAPY	\$ 45.00	
06/27/16		\$ 85.00	
06/27/16	97039 UNLISTED MODALITY (SPECIFY TYPE & TIME)	\$ 50.00	
7/07/16	98940 (CMT); SPINAL, 1-2 REGIONS	\$ 85.00	
1112/10	\$1000 OMMIGION MODULITY OFFICIAL TILE & ITME)	\$ 50.00	
77/07/16 07/07/16 07/12/16 07/12/16 07/12/16	97039 UNLISTED MODALITY (SPECIFY TYPE & TIME) 98940 (CMT); SPINAL, 1-2 REGIONS 97014 ELECTRIC STIMULATION THERAPY 97039 UNLISTED MODALITY (SPECIFY TYPE & TIME)	\$ 45.00 \$ 50.00 \$ 85.00 \$ 45.00 \$ 50.00	

Total Sales Tax : \$ 0.00
Total Late Charges : \$ 0.00
Total Interest Charges : \$ 0.00
Patients-Cash Rcvd : \$ 0.00
Patients-Chks Rcvd : \$ 0.00
Patients-Crdt Crd : \$ 0.00
Payer Payments : \$ 0.00
Total Charges : \$ 5025.00
Total Received : \$ 0.00
Total Adjustment : \$ 0.00

Page 3 Patient: THERA REID

Balance (based on search): \$ 5025.00

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provision, the physician fee schedule amount is compared to the OPPS payment amount and the lower

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amount is used for payment.



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Limiting Charge

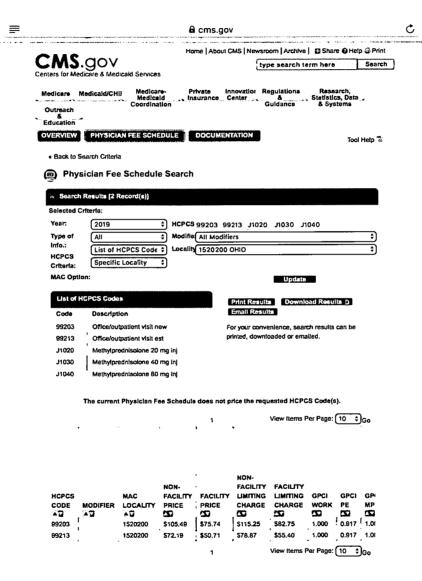
A limiting charge is an upper limit on how much doctors who do not accept Medicare's approved amount as payment in full can charge to people with Medicare. Federal law sets the limit at 15 percent more than the Medicareapproved amount. Some states limit it even further. For example, in New York doctors can only charge 5 percent more than Medicare's approved amount for certain services. This charge is in addition to 20 percent coinsurance (45 percent for mental health services). Providers who opt-out of Medicare are not subject to these limiting charges and can charge as much as they want, if the patient signs an agreement with them prior to receiving care.

« Back to Glossary Index

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CV-2016-09-3928

MICHAEL, KATHRYN

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3/2/2017

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SHIP TO: CLEARWATER BILLING 195 WADSWORTH RD STE 402 WADSWORTH, OH 44281-9504 Page 1 of 1

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Page 2 of 2

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Barberton, OH 44203

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1045 Eagon St 3202 Angleterre Blud

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Bill To Dr. Sam Ghoubrial Flounders Hall 195 Wadsworth Rd. Wadsworth, OH 44281

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5160-1-13.1 Medicaid consumer liability.

- (A) The medicaid payment for a covered service constitutes payment-in-full and may not be construed as a partial payment even when the reimbursement amount is less than the provider's charge. The provider may not collect and/or bill the consumer for any difference between the medicaid payment and the provider's charge or request the consumer to share in the cost through a deductible, coinsurance, co-payment or other similar charge, other then medicaid co-payments as defined in rule 5160-1-09 of the Administrative Code. The provider may not charge the consumer a down payment, refundable or otherwise.
- (B) A medicaid consumer cannot be billed when a medicaid claim has been denied due to:
- (1) Unacceptable or untimely submissions of claims;
- (2) Failure to request a prior authorization; or
- (3) A peer review organization (PRO) retroactively denying services for lack of medical necessity.
- (C) Providers are not required to bill the Ohio department of medicaid (ODM) for medicaid-covered services rendered to eligible consumers. However, providers may not bill consumers in lieu of ODM unless:
- (1) The consumer is notified in writing prior to the service being rendered that the provider will not bill ODM for the covered service; and
- (2) The consumer agrees to be liable for payment of the service and signs a written statement to that effect prior to the service being rendered; and
- (3) The provider explains to the consumer that the service is a covered medicaid service and other medicaid providers may render the service at no cost to the consumer.
- (D) Services that are not covered by the medicaid program, including services requiring prior authorization that have been denied by ODM, may be billed to the consumer when the provisions in paragraphs (C)(1) and (C)(2) of this rule are met.

Effective: 11/28/2014

Five Year Review (FYR) Dates: 09/08/2014 and 11/28/2019

Promulgated Under: 119.03
Statutory Authority: 5164.02

Rule Amplifies: 5164.02

Prior Effective Dates: 6/3/83, 2/11/84, 10/1/84, 7/1/85 (Emer), 9/30/85, 10/1/87, 5/30/02, 1/1/04,

7/1/05, 1/6/06, 02/01/2010



CV-2016-09-3928 MICHAEL, KATHRYN 05/15/2019 20:51:50 PM NFIL Page 40 of 201

CHAPTER 1: OPINIONS ON PATIENT-PHYSICIAN RELATIONSHIPS

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

1.1 Responsibilities of Physicians & Patients

- 1.1.1 Patient-Physician Relationships
- 1.1.2 Prospective Patients
- 1.1.3 Patient Rights
- 1.1.4 Patient Responsibilities
- 1.1.5 Terminating a Patient-Physician Relationship
- 1.1.6 Quality
- 1.1.7 Physician Exercise of Conscience
- 1.1.8 Physician Responsibilities for Safe Patient Discharge from Health Care Facilities

1.2 Special Issues in Patient-Physician Relationships

- 1.2.1 Treating Self or Family
- 1.2.2 Disruptive Behavior by Patients
- 1.2.3 Consultation, Referral & Second Opinions
- 1.2.4 Use of Chaperones
- 1.2.5 Sports Medicine
- 1.2.6 Work-Related & Independent Medical Examinations
- 1.2.7 Use of Restraints
- 1.2.8 Gifts from Patients
- 1.2.9 Use of Remote Sensing & Monitoring Devices
- 1.2.10 Political Action by Physicians
- 1.2.11 Ethically Sound Innovation in Medical Practice
- 1.2.12 Ethical Practice in Telemedicine
- 1.2.13 Medical Tourism

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1.1.1 Patient-Physician Relationships

The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. The relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare.

A patient-physician relationship exists when a physician serves a patient's medical needs. Generally, the relationship is entered into by mutual consent between physician and patient (or surrogate).

However, in certain circumstances a limited patient-physician relationship may be created without the patient's (or surrogate's) explicit agreement. Such circumstances include:

(a) When a physician provides emergency care or provides care at the request of the patient's treating physician. In these circumstances, the patient's (or surrogate's) agreement to the relationship is implicit.

PLAINTIFF'S
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- (b) When a physician provides medically appropriate care for a prisoner under court order, in keeping with ethics guidance on court-initiated treatment.
- (c) When a physician examines a patient in the context of an independent medical examination, in keeping with ethics guidance. In such situations, a limited patient-physician relationship exists.

AMA Principles of Medical Ethics: I,II,IV,VIII

1.1.2 Prospective Patients

As professionals dedicated to protecting the well-being of patients, physicians have an ethical obligation to provide care in cases of medical emergency. Physicians must also uphold ethical responsibilities not to discriminate against a prospective patient on the basis of race, gender, sexual orientation or gender identity, or other personal or social characteristics that are not clinically relevant to the individual's care. Nor may physicians decline a patient based solely on the individual's infectious disease status. Physicians should not decline patients for whom they have accepted a contractual obligation to provide

However, physicians are not ethically required to accept all prospective patients. Physicians should be thoughtful in exercising their right to choose whom to serve.

A physician may decline to establish a patient-physician relationship with a prospective patient, or provide specific care to an existing patient, in certain limited circumstances:

- (a) The patient requests care that is beyond the physician's competence or scope of practice; is known to be scientifically invalid, has no medical indication, or cannot reasonably be expected to achieve the intended clinical benefit; or is incompatible with the physician's deeply held personal, religious, or moral beliefs in keeping with ethics guidance on exercise of conscience.
- (b) The physician lacks the resources needed to provide safe, competent, respectful care for the individual. Physicians may not decline to accept a patient for reasons that would constitute discrimination against a class or category of patients
- (c) Meeting the medical needs of the prospective patient could seriously compromise the physician's ability to provide the care needed by his or her other patients. The greater the prospective patient's medical need, however, the stronger is the physician's obligation to provide care, in keeping with the professional obligation to promote access to care.
- (d) The individual is abusive or threatens the physician, staff, or other patients, unless the physician is legally required to provide emergency medical care. Physicians should be aware of the possibility that an underlying medical condition may contribute to this behavior.

AMA Principles of Medical Ethics: I,VI,VIII,X

1.1.3 Patient Rights

The health and well-being of patients depends on a collaborative effort between patient and physician in a mutually respectful alliance. Patients contribute to this alliance when they fulfill responsibilities they have, to seek care and to be candid with their physicians, for example.

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Physicians can best contribute to a mutually respectful alliance with patients by serving as their patients' advocates and by respecting patients' rights. These include the right:

- (a) To courtesy, respect, dignity, and timely, responsive attention to his or her needs.
- (b) To receive information from their physicians and to have opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives, including the risks, benefits and costs of forgoing treatment. Patients should be able to expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician's objective professional judgment.
- (c) To ask questions about their health status or recommended treatment when they do not fully understand what has been described and to have their questions answered.
- (d) To make decisions about the care the physician recommends and to have those decisions respected. A patient who has decision-making capacity may accept or refuse any recommended medical intervention.
- (e) To have the physician and other staff respect the patient's privacy and confidentiality.
- (f) To obtain copies or summaries of their medical records.
- (g) To obtain a second opinion.
- (h) To be advised of any conflicts of interest their physician may have in respect to their care.
- (i) To continuity of care. Patients should be able to expect that their physician will cooperate in coordinating medically indicated care with other health care professionals, and that the physician will not discontinue treating them when further treatment is medically indicated without giving them sufficient notice and reasonable assistance in making alternative arrangements for care.

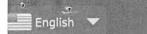
AMA Principles of Medical Ethics: I, IV, V, VIII, IX

1.1.4 Patient Responsibilities

Successful medical care requires ongoing collaboration between patients and physicians. Their partnership requires both individuals to take an active role in the healing process.

Autonomous, competent patients control the decisions that direct their health care. With that exercise of self-governance and choice comes a number of responsibilities. Patients contribute to the collaborative effort when they:

- (a) Are truthful and forthcoming with their physicians and strive to express their concerns clearly. Physicians likewise should encourage patients to raise questions or concerns.
- (b) Provide as complete a medical history as they can, including providing information about past illnesses, medications, hospitalizations, family history of illness, and other matters relating to present health.
- (c) Cooperate with agreed-on treatment plans. Since adhering to treatment is often essential to public and individual safety, patients should disclose whether they have or have not followed the agreed-on plan and indicate when they would like to reconsider the plan.





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Sandra Kurt, Summit County Clerk of Courts

NEED LANGUAGE ASSISTANCE?

Español – 中文 – Deutsch – عربی – Pennsylvania Deitsch – русском – français – Tiếng Việt – Oroomiffa – 한국어 – l'italiano – 日本語 – Nederlands – українською – română

LEARN MORE

SERVICES WE OFFER

We offer primary care, dental, behavioral health and pharmacy services.

LEARN MORE

FIND THE CLOSEST OFFICE TO YOU

CV-2016-09-3928	MICHAEL, KATHRYN	05/15/2019 20:51:50 PM	NFIL	Page 45 of 201
ı	AxessPointe ha	as five locations to c	onveniently serv	e you.
		· · · · · · · · · · · · · · · · · · ·	Tuesday	
		LOCATIONS		
	ACC	ess my patien	IT PORTAL	
	3323			
	Ask questions, r	efill prescriptions or	request appoin	tments,
		LEARN MORE		
				TERED MAG
				ALCON MORE
				E (NCQA
				COCCULIED CONSULT

AxessPointe Community Health Centers are Federally Qualified Health Centers (FQHCs), represented by the OACHC. As an NCQA accredited, patient-centered medical home (PCMH), we are committed to high-quality care and service. We are also a member of the National Health Service Corps – which ensures we have caring, qualified and passionate health care providers.

MISSION

To provide a quality, affordable and compassionate health home for – every patient, every time- in all communities.

VISION

Framed by the precept that health is a human right and not a privilege, our vision is to be recognized as a leader in the delivery of high quality, integrated family-oriented health care and as a model program for community-based primary care. This process requires us to be integral partners with the community in the promotion of health, education and access to care.

You Asked and We Got to the Bottom of It

You Asked and We Got to the Bottom of It: Questions and Answers about

DONATE

VOLUNTEER

CAREERS

WHAT WE DO

Behavioral Health

Dental

Medical

<u>Pharmacy</u>

Women's Health

LOCATIONS

<u>Arlington</u>

Barberton

<u>Broadway</u>

Kent

Portage Path

OTHER

About FQHC

In The News

Patient Bill of Rights

Terms and Conditions

HIPPA/Privacy Policy

GET INVOLVED

Donate

Careers

Volunteer

This site uses cookies. By continuing to browse the site, you are agreeing to our use of cookies.

OK

Learn More

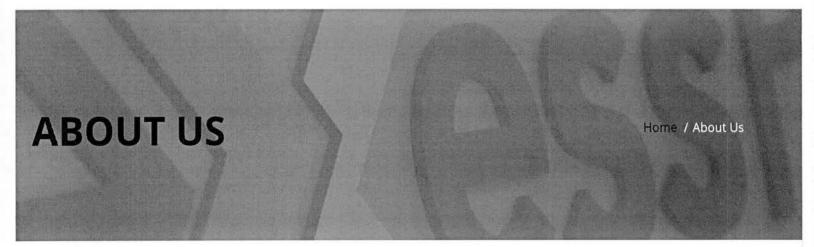


f ⊻ in 🛚

888-975-9188

We accept Medicaid and Medicare





ABOUT US

AxessPointe Community Health Centers, originally named Akron Community Health Resources, Inc., opened its doors in 1995 after receiving funds from the Bureau of Primary Health Care to establish the first federally qualified health center in Summit County.

AxessPointe has five current sites in Northeast Ohio, including three in Akron, one in Kent and one in Barberton. As an FQHC, we deliver primary medical and dental care in medically underserved areas. AxessPointe also provides behavioral health, women's health and pharmacy services.

While our focus is on uninsured, underinsured and Medicaid/Medicare patients who may not have access to affordable health care, our services are welcome to all. Our health care teams provide diagnosis, treatment and preventive medical and dental services. We accept Medicaid, Medicare, most private insurances and provide a sliding-fee scale based on family size and income.

AxessPointe Community Health Centers is a Federally Qualified Health Center (FQHC), represented by the OACHC. FQHCs receive operating grants under Section 330 of the

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United States Public Health Service Act. In order to comply with federal law, FQHCs must be established as a not-for-profit corporation and the majority of the board of directors must be consumers of the services provided by the facility.

The OACHC, Ohio Association of Community Health Centers, is a non-profit organization that represents Ohio's FQHCs. The mission of the OACHC is to ensure high-quality affordable health care for all Ohioans through the growth and development of Ohio's Community Health Centers.

As a National Committee of Quality Assurance (NCQA) certified <u>patient-centered</u> <u>medical home (PCMH)</u>, we are committed to high-quality care and service. We are also a member of the National Health Service Corps – which ensures we have caring, qualified and passionate health care providers through loan repayment packages.

Learn AxessPointe's History

FTCA DEEMED FACILITY

This health center receives HHS funding and has Federal Public Health Service (PHS) deemed status with respect to certain health or health-related claims, including medical malpractice claims, for itself and its covered individuals.

WHAT IS A PATIENT-CENTERED MEDICAL HOME (PCMH)?

A PCMH is a care delivery model where your treatment is coordinated through your primary care provider to make sure you receive the care you need when and where you need it, in a way that is understandable. The model is centered around communication and focused on you and your health. Our goal at AxessPointe is to help you feel your best. Watch this <u>short video</u> to learn more.

LEADERSHIP TEAM



Judith Banks, MPA, C SHL, C MHFA

Human Resources Director

CLEVELAND CLINIC AKRON GENERAL HEALTH SYSTEM

In 2014, AxessPointe and Cleveland Clinic Akron General Health System came into agreement to create a unique experience for two of the Akron General Residency Programs. Residents in the OB/GYN and Internal Medicine programs gain experience

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by seeing patients in AxessPointe's Women's Health and Internal Medicine offices. Patients are seen by medical doctors who are then overseen by attending physicians. Internal Medicine is a three-year residency program, with 10 new residents each year. Women's Health is a four-year residency program with four new residents each year. For more information, please contact Medical Education & Research at Akron General.

BOARD OF DIRECTORS

Jay Williamson, *President*Jack Evans, *Vice President*Greta Lax, *Treasurer*Bernett Williams, *Secretary*Rita Aggarwal
Roxia Boykin
Roula Braidy
Rebecca Callahan

Lydia Cook
David Hamilton
Christina Hodgkinson
Edwin Hubbard, Jr.
Joshua Moraghan
Karen Mullen
Len Rose
Joanne Tate

AxessPointe Community Health Centers, Inc. Receives Grant to Purchase Medication Delivery Vehicle

AxessPointe Community Health Centers, Inc. Receives Grant to Purchase Medication Delivery Vehicle March 12, 2019 - AxessPointe Community Health Centers, Inc. has added a new element to the list of services they provide to their patients,...

Read more >

[https://axesspointe.org/medication-delivery-vehicle/]

You Asked and We Got to the Bottom of It

You Asked and We Got to the Bottom of It: Questions and Answers about

 Colon Cancer and Colon Health By: Vikil Girdhar, MD Your questions, our answers! March is National Colorectal Cancer Awareness Month, which is a great time to stress the...

Read more >

[https://axesspointe.org/youasked-and-we-got-to-thebottom-of-it/]

We HEART Your Health

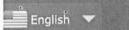
We HEART Your Health! Tips on Preventing Heart Disease By: E. Demond Scott, MD, MPH February is American Heart Month, a time to focus on the importance of keeping a strong and healthy heart. It's a great time to educate communities about...

Read more >

[https://axesspointe.org/we-heart-your-health/]

DONATE

VOLUNTEER





888-975-9188

We accept Medicaid and Medicare



MEDICAL SERVICES

Home / Medical Services

Regular visits to the doctor are important! Having regular medical check-ups will help create a good relationship with your doctor and will help keep your body in check. If your family has a history of certain medical conditions, regular visits can help you learn your potential risk of these conditions. This can also help find any possible problems before they start. Regular check-ups also help you stay updated on different screenings such as blood pressure, cholesterol checks and certain types of cancer screenings. By getting the right medical services and screenings, you are taking an active role in your health.

At AxessPointe, our primary goal is to provide affordable, quality health care for the community. Both physicians and nurse practitioners are available to care for you and your family. Call 888.975.9188 and schedule your appointment!

SERVICES

ADULT AND CHILDREN'S HEALTH



VISION SCREENING

Before your appointment, it is important to write down any questions you might have for your doctor. There is no question that is too small, even changes in your eating and sleeping habits are important to mention. If you know of illnesses in your family, you should let your doctor know – family history can possibly affect your health. It's also a good idea to find out if you are current on your vaccinations or health screenings. Another topic to discuss are your exercise and eating habits. Letting your health care provider know of any changes and questions you may have is a great way to start taking control of your health. Not sure what questions you should ask during your visit? The Agency for Healthcare Research and Quality has information for patients and offers tips on questions to ask during your check-up: The 10 Questions You Should Know.

ARLINGTON





888-975-9188

We accept Medicaid and Medicare



LOCATIONS

Home / Locations

We have five, convenient locations to serve you. We also have an after-hours service available. To contact any of our sites or after-hours service, please call 888-975-9188.

Arlington

Barberton

Broadway

Kent

Portage Path

AXESSPOINTE ARLINGTON

1400 S. Arlington St. Suite 38 Akron, OH 44306 330-724-5471

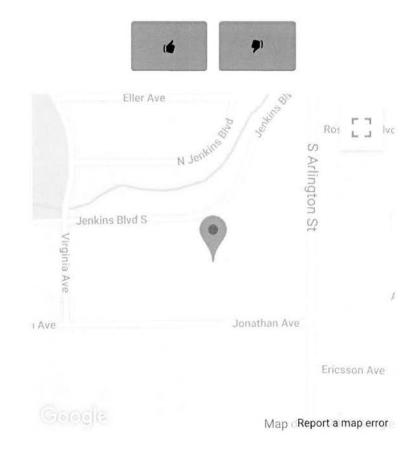
Monday – Friday 8 AM – 6 PM Saturday 8 AM – 2 PM

Site Manager: Denico Buckley

ARLINGTON PHARMACY

Monday, Tuesday, Thursday, Friday 8:30 AM – 5:30 PM Wednesday 9 AM – 6 PM Saturday 8:30 AM – 12:30 PM

Rate this location:



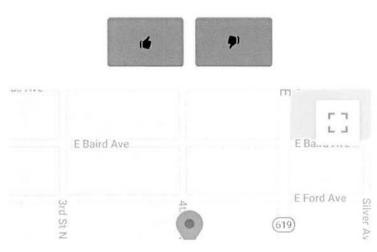
AXESSPOINTE BARBERTON

390 Robinson Ave. Suite E Barberton, OH 44203 330-564-2697

Monday – Friday 8 AM – 6 PM Saturday 8 AM – 2 PM

Site Manager: Deleshia Fitzgerald

Rate this location:



AXESSPOINTE BROADWAY

Internal Medicine – Suite 103 Women's Health – Suite 203 676 S. Broadway St. Akron, OH 44311

Internal Medicine: 330-564-8650 Women's Health: 330-564-8660

Monday – Friday 8 AM – 6 PM Select Tuesdays until 7 PM

Site Manager, Internal Medicine: Carrie Schrock Site Manager, Women's Health: LaTisha Moore

BROADWAY PHARMACY

Monday, Tuesday, Thursday, Friday 8:30 AM – 5:30 PM Wednesday 9 AM – 6 PM Saturday CLOSED

Rate this location:



Map Report a map error

AXESSPOINTE KENT

143 Gougler Ave. Kent, OH 44240 330-673-1016

Monday - Friday 8 AM - 6 PM Saturday 8 AM - 2 PM

Site Manager: Stephanie Schulda

KENT PHARMACY

Monday, Tuesday, Thursday, Friday 8:30 AM - 5:30 PM Wednesday 9 AM - 6 PM Saturday CLOSED

Rate this location:



AXESSPOINTE AT PORTAGE PATH BEHAVIORAL HEALTH

340 S. Broadway St. Akron, OH 44308 330-548-0958

Monday, Tuesday 8:30 AM - 6 PM Thursday 9 AM - 7 PM Friday 8:30 AM - 1 PM

Site Manager: Deleshia Fitzgerald

Rate this location:





CARE FOR THE UNINSURED

Faithful Servants Care Center provides free urgent health care services with a Christ-like compassion for those without insurance and the economic means to access traditional medical care.

We serve all age groups with minor, urgent and acute illnesses and injuries.

Obstetrical and mental health care services are not provided. We do not process S.S.I. forms or perform disability assessments.

LEARN MORE

2 12.745
Patients Helped

Doctors, Caretakers, and Volunteers

\$602.231
Value Of Free Office
Visits in 2017

1.700
Prescriptions Provided
Annually







Serving all ag



Injurie

We help those

sprains, back

bones

Sudden Illness

We provide care for a sudden

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Sole tilloat,

stomach pain,

rash, ache, and

more



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and diabetes

checks as well

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treatment for

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Referrals for

emergencies

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OUR STORY RECENT NEWS



Free Urgent Medical Care Now Serving Windham

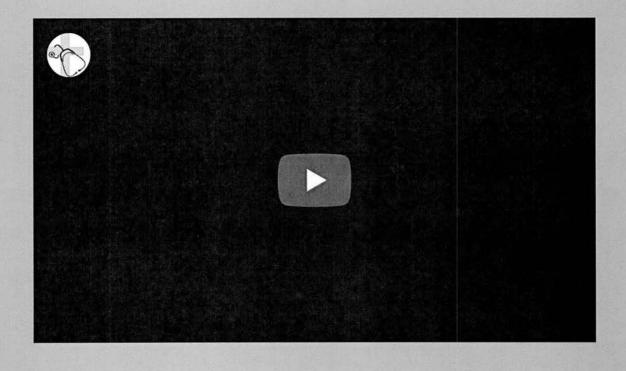
> READ ARTICLE

Faithful Servants Living Out Faith By Providing Free Urgent Care To Uninsured

> READ ARTICLE

HEARTBEATS

Heartbeats is a moving story about how a team of medical professionals and Summa Health collaborated with US to provide a man from Ghana with a gift of heart surgery. Hear from three doctors about the process and how important this program is to the Akron community.



WATCH VIDEO GET INVOLVED DONATE NOW

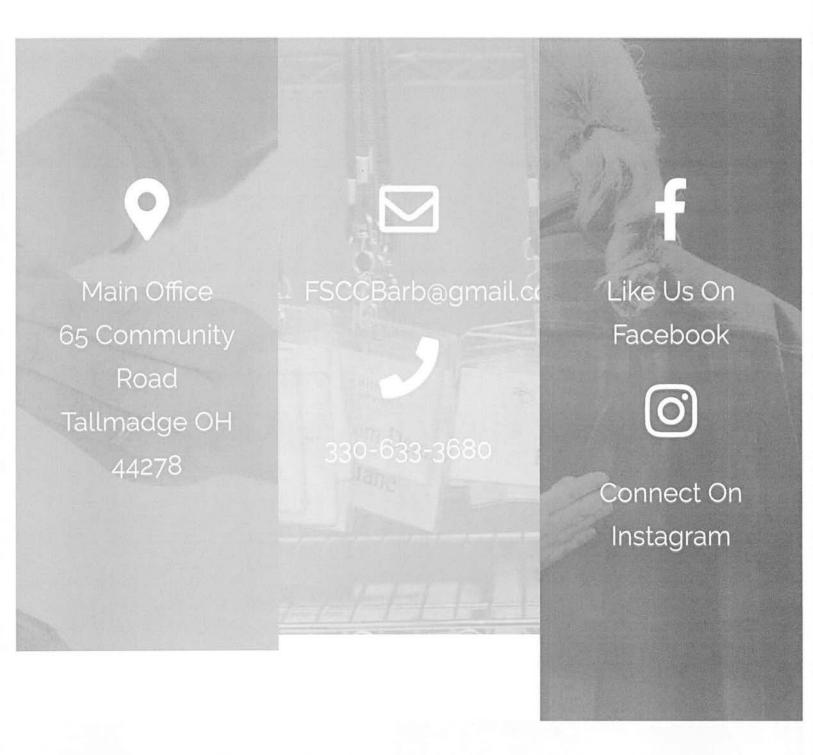


I went here with a simple stomach ache and these people helped me above and beyond what I thought was necessary.

Found out within a few days that my gall bladder was the problem and had it removed within a few days. I am a missionary and this all was resolved in time to return to Costa Rica and continue serving there without a problem. I love these people.

Tara

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SERVICES

TREATMENT SERVICES WE PROVIDE



Page 68 of 201

We provide urgent medical care conditions for minor illnesses and injuries.

- Sudden illness (a cough or cold, sore throat, stomach pain, rash, headache, earache, etc.).
- Cuts, sprains, back pain, possible broken bones.
- Blood pressure and diabetes checks.
- Initial treatment for tooth or eye injury or infection.
- Referrals for emergency or follow-up care, including mental health care.
- Spiritual and emotional support.
- Free or discounted prescriptions.

Referrals for continuing care of ongoing medical problems will be made to an appropriate health care clinic.

Some services not provided at all our locations. Please check our Locations page before visiting us.

SERVICES WE DO NOT PROVIDE

- × Obsterical
- × Mental Health
- ★ Life-threatening conditions
- ★ S.S.I. forms of disability assessments

SAFETY INFORMATION

We do not prescribe, or have on site, any controlled substances or narcotics, and reserve the right to refuse care based on patient misconduct, the capacity of clinic staff, or other constraints beyond our control.

If you or a loved one are experiencing a life-threatening condition call 911.

CV-2016-09-3928

- Annual income at or below 200% of the federal poverty guidelines, Status must be verified.
- Without medical insurance OR With Medicare or Medicaid but lacking a primary care provider (depending on location)
- Must bring photo ID
- Patients under age 18 must be accompanied by a parent/guardian with a valid photo ID
- Must bring Medicaid or
 Medicare card if applicable



Our care center is open to all

qualified patients, regardless of religious beliefs. Pastoral support and counseling are available to those who desire it.

SPECIALTY CARE

We do have capability of referring to in-house or external specialists when deemed necessary by evaluating physicians.



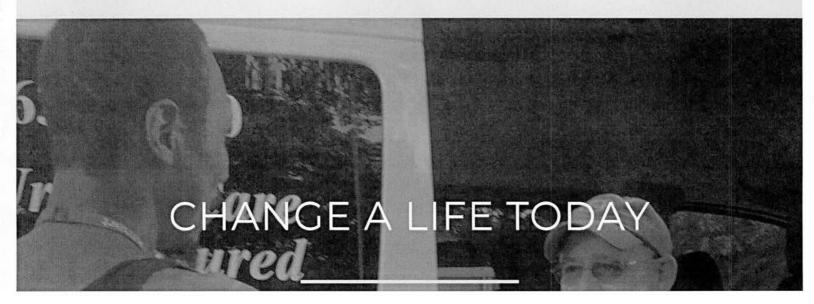
I went here with a simple stomach ache and these people helped me above and beyond what I thought was necessary.

Found out within a few days that my gall bladder was the problem and had it removed within a few days. I am a missionary and this all was resolved in time to return to Costa Rica and continue serving there without a problem. I love these people.

Tara

God's faithful servant has no desire for people to say or to give to him, or what he likes to hear or see, for his first and greatest aim is to hear what is most pleasing to God.

Saint Augustine





LOCATIONS



MAIN OFFICE

Tallmadge Ohio

65 Community Road, Tallmadge OH 44278 / Across

Community Road from Tallmadge Community Center and Tallmadge library

Hours:

Sunday 5:30pm-8:30pm

Monday 5:30pm-8:30pm

Tuesday 5:30pm-8:30pm

Wednesday 5:30pm-8:30pm

Thursday 5:30pm-8:30pm

Friday 5:30pm-8:30pm

Saturday CLOSED

Services Offered:

- Sudden illness (cough or cold, sore throat, stomach pain, rash, headache, ear ache, etc.)
- Cuts, sprains, back pain, possible broken bones
- Blood pressure and diabetes checks
- Initial treatment for tooth or eye injury or infection
- Referrals for emergency or follow-up care, including mental health care.
- Spiritual and emotional support
- Free or discounted prescriptions

Please note we do **not** provide the following services:

Obstetrical, Mental Health, Life Threatening Conditions,

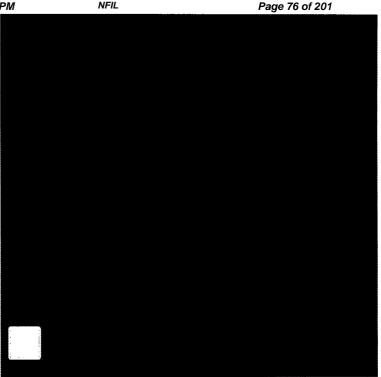
S.S.I. Forms or Disability Assessments

Eligibility:

Adults and children with family income at or below 200% of the federal poverty guidelines and without medical insurance. We do not accept patients at this location with Medicare or Medicaid.

Safety Information:

We do not prescribe, or have on site, any controlled substances or narcotics, and reserve the right to refuse care based on patient misconduct, capacity of clinic staff.



Directions:

- From Interstate 76 east exit at exit 29
 (Tallmadge/Mogadore) turn left to Tallmadge Circle.
- From Tallmadge circle take East Avenue toward
 Brimfield, turn left on Community Road, FSCC is on
 your left adjacent to Northeast Family Healthcare.

THE FRONT PORCH

Akron, OH

798 Grant St., Akron, OH 44311

Hours:

Tuesday 5:30pm-8:30pm (PEDIATRIC PATIENTS ONLY) Wednesday 5:00pm-8:00pm (ALL PATIENTS)

Please note, we see all patients here on Wednesdays. On Tuesdays, we only see pediatric patients.

Services Offered:

- Sudden illness (cough or cold, sore throat, stomach pain, rash, headache, ear ache, etc.)
- Cuts, sprains, back pain, possible broken bones
- Blood pressure and diabetes checks
- Initial treatment for tooth or eye injury or infection
- Referrals for emergency or follow-up care, including mental health care.
- Spiritual and emotional support
- Free or discounted prescriptions

Please note we do not provide the following services:

Obstetrical, Mental Health, Life Threatening Conditions,

S.S.I. Forms or Disability Assessments

Eligibility:

Adults and children with family income at or below 200% of the federal poverty guidelines and either of the following:

· Without medical insurance



With Medicaid but lacking a primary care provider

Safety Information:

We do not prescribe, or have on site, any controlled substances or narcotics, and reserve the right to refuse care based on patient misconduct, capacity of clinic staff, or other constraints beyond our control.

The Front Porch is part of South Street Ministries.

HAVEN OF REST

Akron Ohio

175 E. Market St, Akron, OH 44308

Hours:

Thursday 6:00pm-9:00pm (ALL PATIENTS)

Services Offered:

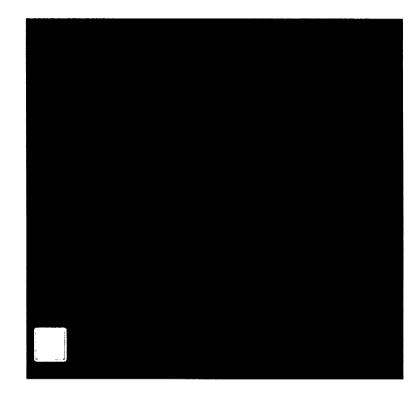
- Sudden illness (cough or cold, sore throat, stomach pain, rash, headache, ear ache, etc.)
- abla Cuts, sprains, back pain, possible broken bones
- Dlood pressure and diabetes checks
- Initial treatment for tooth or eye injury or infection
- Referrals for emergency or follow-up care, including mental health care.
- Spiritual and emotional support
- Free or discounted prescriptions

Please note we do **not** provide the following services:

Obstetrical, Mental Health, Life Threatening Conditions,

S.S.I. Forms or Disability Assessments

Eligibility:



NFIL

Adults and children with family income at or below 200% of the federal poverty guidelines and without medical insurance. We do not accept patients at this location with Medicare or Medicaid.

Safety Information:

We do not prescribe, or have on site, any controlled substances or narcotics, and reserve the right to refuse care based on patient misconduct, capacity of clinic staff, or other constraints beyond our control.

WINDHAM / PORTAGE COUNTY

Renaissance Family Center

9005 Wilverne Drive, Windham, OH 44288

Hours:

Sunday CLOSED

Every Mon 4:00pm-7:00pm

1st Wed 9:00am-11:30am

2nd Wed 1:30pm-4:00pm

3rd Wed 4:00pm-7:00pm

4th Wed 9:00am-11:30am

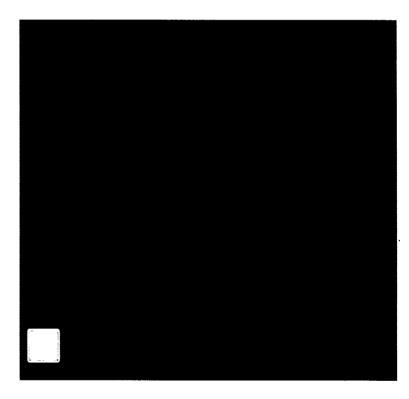
Saturday CLOSED

Appointments available at this location on Wednesdays.

Email Barb at fsccbarb@gmail.com or call our main phone number.

Services Offered:

Sudden illness (cough or cold, sore throat, stomach



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- pain, rash, headache, ear ache, etc.)
- Cuts, sprains, back pain, possible broken bones
- Blood pressure and diabetes checks
- Initial treatment for tooth or eye injury or infection
- Referrals for emergency or follow-up care, including mental health care.
- Spiritual and emotional support
- Free or discounted prescriptions

Please note we do **not** provide the following services:

Obstetrical, Mental Health, Life Threatening Conditions,

S.S.I. Forms or Disability Assessments

Eligibility:

Adults and children with family income at or below 200% of the federal poverty guidelines and either of the following:

- · Without medical insurance
- With Medicare or Medicaid but lacking a primary care provider

Safety Information:

We do not prescribe, or have on site, any controlled substances or narcotics, and reserve the right to refuse care based on patient misconduct, capacity of clinic staff, or other constraints beyond our control.

Free Dedicated Speciality Clinics at Tallmadge

Faithful Servants Care Center offers

free dedicated clinics including:

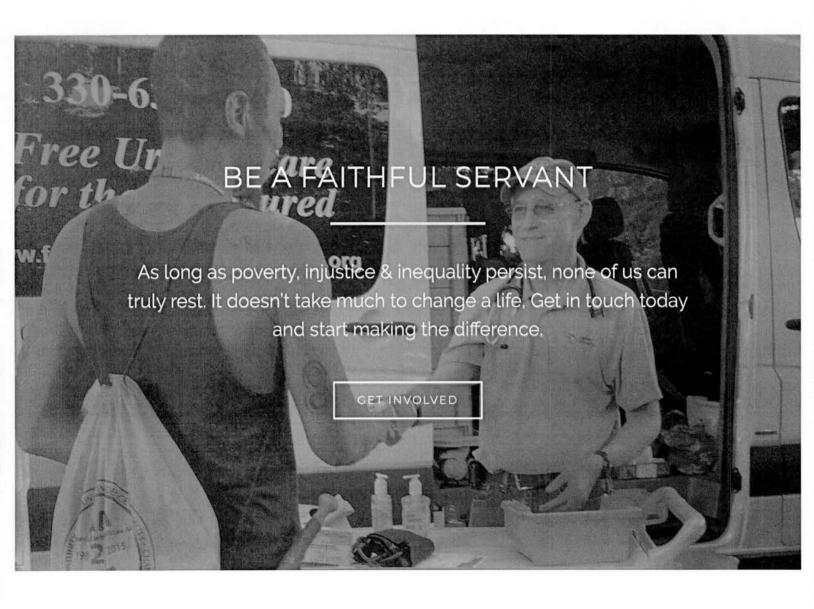
Podiatry, Dermatology, Orthopedic,

Diabetic and Women's Health.

This video explores the services and

professional volunteers who make up

these ministries





Clinic Quick Facts



VOLUNTEER DOCTORS



ACTIVE CLINIC PATIENTS



SPECIALTIES OFFERED



Free Medical Clinic

At OPEN M, we are dedicated to reducing health disparities and providing patient-centered services to people with limited access to medical care. Since 1995, the OPEN M clinic has provided care for uninsured adults throughout Summit County. We offer comprehensive medical care that is focused on chronic disease management. Enrolled patients receive all services, including medications and diabetic supplies, free of charge.

OPEN M Patient Portal

Access your Clinic Medical Records Online

Click the button to the right to log-in to your Clinic medical records. Stay up to date with all your appointments and ongoing treatments.

& Click Here to Access Your Records (https://17377.portal.athenahealth.com)

No Walk-Ins, Call us to Enroll! -

We are here for you!

We provide primary and specialty healthcare. Our specialties include chiropractic, dermatology, dental, endocrinology, nephrology, neurology, nutrition, optometry, orthopedics, pulmonology, physical therapy, podiatry, psychiatry, urology, women's health, and behavioral health.

Our services include:

A full-service formulary pharmacy that provides free medicine

Basic in-house lab testing, such as blood work and urinalysis

Help patients sign up for Medicaid or find affordable insurance through the healthcare marketplace

Preventive health care

We focus on educating patients about:

MICHAEL, KATHRYN 05/15/2019 20:51:50 PM

РМ

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Specific diseases
Tobacco Cessation
Nutrition
The larger health care system

We focus on educating patients about

Specific diseases
Tobacco Cessation
Nutrition
The larger health care system

OPEN M is a member of both the *Ohio Association of Free Clinics* (OAFC) and the *National Association of Free Clinics* (NAFC).

For more information, call 330-434-0110 x 413 or email clinic2@openm.org (mailto:clinic2@openm.org).

Help OPEN M by donating today!

DONATE NOW (HTTPS://OPENM.ORG/DONATE/)

OUR MISSION

The mission of OPEN M, a Christian ministry, is to provide pathways out of poverty for all by feeding the hungry, caring for the sick, and strengthening the community.

- 941 Princeton St., Akron, Ohio 44311
- 330-434-0110



Info@Openm.org (Mailto:info@Openm.org)

SERVICES

Community Works Connection (https://openm.org/cwc)

Food Programs (https://openm.org/food-programs/)

Medical Clinic (https://openm.org/clinic)

Other Services (https://openm.org/other-servies)

NEWSLETTER SIGNUP

Stay in the loop. Sign up for our e-news updates!



ENTER YOUR EMAIL

SUBSCRIBE

FOLLOW US ON SOCIAL MEDIA









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FOLLOW US ON INSTAGRAM









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EXTENDED TO NOVEMBER 15, 2018

.orm **990**

Department of the Treasury

Internal Revenue Service

Return of Organization Exempt From Income Tax

Under section 501(c), 527, or 4947(a)(1) of the Internal Revenue Code (except private foundations)

Do not enter social security numbers on this form as it may be made public.
 Go to www.irs.gov/Form990 for instructions and the latest information.

2017
Open to Public Inspection

A For the 2017 calendar year, or tax year beginning and ending									
B Check if applicable		C Name of organization		D Employer identification number					
		e:	D Employer Identifi	Cation name					
	Addre	SUMMA HEALTH GROUP RETURN							
			90-0640432						
-	cheng Tinitial		(<u> </u>					
retur		, , , , , , , , , , , , , , , , , , , ,	om/suite	E Telephone number					
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_	ated TAmen	City or town, state or province, country, and ZIP or foreign postal code	G Gross roceipts \$ 1,029,067,159.						
\vdash	return Applic	AKKON, OH 44309-2090	H(a) Is this a group return						
L	_tion pendi	Finame and address of principal officer: 1 - CDIII PORD DEVENI, I	for subordinates? X Yes No						
		SAME AS C ABOVE	H(b) Are all subordinates included? XYes No If "No," attach a list. (see instructions)						
			WWW.SUMMAHEALTH.ORG						
		organization: X Corporation Trust Association Other	L Year o	of formation:	A State of legal domicile:				
Pa	art I	Summary							
ø	1	Briefly describe the organization's mission or most significant activities: THE MISSION OF SUMMA HEALTH IS							
Governance		TO PROVIDE THE HIGHEST QUALITY, COMPASSION							
ern		Check this box if the organization discontinued its operations or disposed	of more	than 25% of its net as	1				
Š		Number of voting members of the governing body (Part VI, line 1a)			41				
જ		Number of independent voting members of the governing body (Part VI, line 1b)			34				
ies		Total number of individuals employed in calendar year 2017 (Part V, line 2a)			7595				
Activities &	6	Total number of volunteers (estimate if necessary)		6	1722				
Act		Total unrelated business revenue from Part VIII, column (C), line 12			7,779,226.				
	b	Net unrelated business taxable income from Form 990-T, line 34			-726,334.				
			<u> </u>	Prior Year	Current Year				
e ne	i .	Contributions and grants (Part VIII, line 1h)		2,449,196.	1,017,693.				
/eu	l .	Program service revenue (Part VIII, line 2g)		89,432,983.	980,455,645.				
Revenue	ì	Investment income (Part VIII, column (A), lines 3, 4, and 7d)		4,807,420.	8,423,490.				
	ł	Other revenue (Part VIII, column (A), lines 5, 6d, 8c, 9c, 10c, and 11e)		17,836,327.	11,330,107.				
		Total revenue · add lines 8 through 11 (must equal Part VIII, column (A), line 12)		1,014,525,926.	1,001,226,935.				
	l .	ts and similar amounts paid (Part IX, column (A), lines 1-3)		246,200.	151,500.				
		Benefits paid to or for members (Part IX, column (A), line 4)		0.	0.				
Expenses		Salaries, other compensation, employee benefits (Part IX, column (A), lines 5-10)	4	56,353,797.	472,335,028.				
ĕ	16a	Professional fundraising fees (Part IX, column (A), line 11e)	;···	0.	0.				
Х		Total fundraising expenses (Part IX, column (D), line 25) 2,730,993		25 500 242	FF4 000 00C				
		Other expenses (Part IX, column (A), lines 11a-11d, 11f-24e)		35,589,343.					
	1	Total expenses. Add lines 13-17 (must equal Part IX, column (A), line 25)		92,189,340.	1,026,495,454.				
کۆ ة	19	Revenue less expenses, Subtract line 18 from line 12		22,336,586.	-25,268,519.				
15 0			Red	jinning of Current Year	End of Year				
Sse	20	Total assets (Part X, line 16)	···	1,171,917,505.	1,304,834,315.				
Net Assets (Fund Balanc	21	Total liabilities (Part X, line 26)		88,953,590.	949,419,049.				
	rt II	Net assets or fund balances. Subtract line 21 from line 20	3	82,963,915.	355,415,266.				
		Ities of perjury, I declare that I have examined this return, including accompanying schedules and	ad atatama	unta and to the boot of m	u beautidae and halfaf. ikin				
		t, and complete. Declaration of preparer (other than officer) is based on all information of which p			y knowledge and delier, it is				
uue,	COLLEC	t, and complete, declaration of preparer (other than officer) is based on all information of which p	preparer	nas any knowledge.					
Sign		Signature of officer		Date					
		KEITH COLEMAN, SR VP, CFO, TREAS							
Her	е	Type or print name and title							
			T II.	ale Cherk	PTIN				
Daid	1	Print/Type preparer's name Preparer's signature ZACK FORTSCH Preparer's signature	- 1						
Paid Preparer Use Only				T con timpio)	42-0714325				
				Firm's EIN	34-0114343				
USE	Jiny	Firm's address 1 S. WACKER DRIVE, STE 800 CHICAGO, IL 60606		Dhoon no 21	2-634-3400				
Mari	the	RS discuss this return with the preparer shown above? (see instructions)		Frions no. 3 T	X Yes No				
ividy	0.10 11	to propage this retaint with the brehater shown above ((266 illottingficite)			Lear 162 L				

PLAINTIFF'S EXHIBIT 35 LHA For Paperwork Reduction Act Notice, see the separate instructions.

Form 990 (2017)

SCHEDULE H (Form 990)

CV-2016-09-3928

Department of the Treasury Internal Revenue Service

Hospitals

► Complete if the organization answered "Yes" on Form 990, Part IV, question 20. Attach to Form 990.

► Go to www.irs.gov/Form990 for instructions and the latest information.

OMB No. 1545-0047 Open to Public Inspection

Name of the organization

Employer identification number

SUMMA HEALTH GROUP RETURN

90-0640432

Par	rt i Financiai Assistance a	and Certain Of	ner Commu	iity benefits at	COSI				
								Yes	No
1a	Did the organization have a financial	assistance policy	during the tax ye	ar? If "No," skip to	question 6a		1a	X	
b	If "Yes," was it a written policy? If the organization had multiple hospital facilities, indicate which of the following best describes application of the financial assistance policy to its various hospital					1b	Х		
2	facilities during the tax year. Applied uniformly to all hospital facilities Applied uniformly to most hospital facilities								
			СШ Арріі	ed uniformly to mo	st nospitar raciilities	•			
_	Generally tailored to individual	•							
3	Answer the following based on the financial assistance eligibility criteria that applied to the largest number of the organization's patients during the tax year. Did the organization use Federal Poverty Guidelines (FPG) as a factor in determining eligibility for providing free care?								
а	•	•	•		•		_	<u>x</u>	
	f "Yes," indicate which of the following was the FPG family income limit for eligibility for free care: 100%					3a			
b		id the organization use FPG as a factor in determining eligibility for providing discounted care? If "Yes," indicate which							
	of the following was the family income limit for eligibility for discounted care:						3b	X	
	200% 250% 300% 350% 400% Other								1
С	If the organization used factors other than FPG in determining eligibility, describe in Part VI the criteria used for determining								
	eligibility for free or discounted care. Include in the description whether the organization used an asset test or other								
	threshold, regardless of income, as a factor in determining eligibility for free or discounted care. Did the organization's financial assistance policy that applied to the largest number of its patients during the tax year provide for free or discounted care to the								
4	"medically indigent"?						4	X	
5a	Did the organization budget amounts for	free or discounted ca	re provided under	its financial assistance	policy during the ta	cyear?	5a	X	
	If "Yes," did the organization's finan						5b	Х	
С	If "Yes" to line 5b, as a result of bud	_							
	care to a patient who was eligible fo						5с		X
	Did the organization prepare a comm						6a	X	
b	If "Yes," did the organization make i	t available to the p	ublic?	•••••			6b	X	
	Complete the following table using the workshee	ets provided in the Sched	lule H instructions. Do	not submit these worksho	ets with the Schedule H	<u> </u>			
7	Financial Assistance and Certain Ot			1/2/	(d) 5:	(2)	72		
Financial Assistance and (a) Number of activities or served (b) Persons served (c) Total community benefit expense revenue				(e) Net community benefit expense	(f) Percent of total expense				
	ans-Tested Government Programs	programs (optional)	(optional)				· · · · ·	expense	
а	Financial Assistance at cost (from			15 640 506		40.004.055	۱ ,	21	α.
	Worksheet 1)			45,648,796.	32,441,841.	13,206,955.		.21	5
b	Medicaid (from Worksheet 3,			171 226 222	131 050 045	40 076 400	,	60	۵
	column a)			171,336,333.	131,259,845.	40,076,488.		.68	5
С	Costs of other means-tested								
	government programs (from								
	Worksheet 3, column b)			1					
d	Total Financial Assistance and			216 095 120	162 701 696	E2 202 442	۸ ا	.89	Q.
	Means-Tested Government Programs			216,985,129.	163,701,686.	53,283,443.	- 1	• 0 3	0
_	Other Benefits								
е	Community health improvement services and								
	community benefit operations								
	(from Worksheet 4)			8,281,454.	116,975.	8,164,479.		.75	%
	Health professions education			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	110,3730	0,202,275.		•,,,	
•	(from Worksheet 5)			40,791,270.	12,506,530.	28,284,740.	2	.60	ક્ષ
	Subsidized health services			1	,,,	,,	 		<u></u>
9	(from Worksheet 6)			28,555,612.		28,555,612.	2	.62	8
h	Research (from Worksheet 7)			7,604,356.	503,271.	7,101,085.		.65	
	Cash and in-kind contributions			1	, = - = -	, ,			
•	for community benefit (from								
	Worksheet 8)			1,380,438.		1,380,438.		.13	ક
j	Total. Other Benefits			86,613,130.	13,126,776.	73,486,354.	6	.75	
	Total. Add lines 7d and 7j			303,598,259.	176,828,462.	126,769,797.	11	.64	8

CV-2016-09-3928

Schedule O (Form 990 or 990-EZ) (2017) **Employer identification number** Name of the organization SUMMA HEALTH GROUP RETURN 90-0640432 EDUCATION OF ITS PHYSICIANS AND HEALTHCARE PROFESSIONALS. THE AKRON AND ST. THOMAS CAMPUSES ARE TEACHING AFFILIATES OF THE NORTHEAST OHIO MEDICAL UNIVERSITY (NEOMED) AND INCLUDE A STAFF OF PHYSICIANS AND ACCREDITED RESIDENCY AND FELLOWSHIP PROGRAMS THAT FOSTER A DYNAMIC MEDICAL ENVIRONMENT. APPROXIMATELY 90 RESIDENTS AND FELLOWS GRADUATE FROM THE AKRON CAMPUS'S MEDICAL EDUCATION PROGRAMS EACH YEAR. THE BARBERTON CAMPUS HAS A FAMILY PRACTICE RESIDENCY PROGRAM AFFILIATED WITH NEOMED ALONG WITH PROVIDING EDUCATIONAL ROTATIONS FOR MEDICAL STUDENTS. SUMMA HEALTH SYSTEM- BARBERTON CAMPUS SUMMA HEALTH SYSTEM- BARBERTON CAMPUS IS A 500,000 SQUARE FOOT ACUTE CARE TEACHING HOSPITAL LOCATED ON NEARLY 16 ACRES, LOCATED APPROXIMATELY 10 MILES SOUTHWEST OF AKRON, OHIO. THE HOSPITAL HAS 251 THE BARBERTON CAMPUS PROVIDES THE COMMUNITY WITH EASY LICENSED BEDS. ACCESS TO COMPREHENSIVE, HIGH-QUALITY CANCER SERVICES AT THE COMMISSION ON CANCER ACCREDITED PARKVIEW PAVILION, AS WELL AS THE FULL SPECTRUM OF CARDIOVASCULAR DISEASE CARE INCLUDING DIAGNOSTIC, INTERVENTIONAL AND SURGICAL SERVICES, ALONG WITH A VARIETY OF OUTPATIENT SERVICES. PART III LINE 4D - OTHER PROGRAM SERVICES - CONTINUED: CHARITY CARE IN 2017, SUMMA HEALTH PROVIDED CHARITY CARE AT AN ESTIMATED NET COST OF OVER \$13.2 MILLION. THIS AMOUNT REPRESENTS THE NET COST ASSOCIATED WITH PROVIDING THE CARE AND DOES NOT INCLUDE BAD DEBT. PATIENTS WITH INCOME UP TO 200% OF THE FEDERAL POVERTY INCOME GUIDELINES OR WHO HAVE A HOSPITAL BILL THAT EXCEEDS 25% OF THEIR GROSS ANNUAL FAMILY INCOME ARE

CV-2016-09-3928

Schedule O (Form 990 or 990-EZ) (2017) Page 2 **Employer identification number** Name of the organization SUMMA HEALTH GROUP RETURN 90-0640432 ELIGIBLE TO APPLY FOR FULLY DISCOUNTED CHARITY CARE ASSISTANCE. IN ADDITION, THERE IS A SLIDING SCALE DISCOUNT PROGRAM FOR THOSE WITH INCOMES BETWEEN 200% AND 400% OF THE FEDERAL POVERTY INCOME GUIDELINES. IN 2017, THE CHARITY CARE PROGRAM (INCLUDING HOSPITAL CARE ASSURANCE PROGRAM) BENEFITED APPROXIMATELY 17,900 PATIENT ENCOUNTERS. MEDICAID SHORTFALL HISTORICALLY, OHIO MEDICAID REIMBURSEMENTS HAVE NOT COVERED THE COST OF PROVIDING THE CARE TO PROGRAM BENEFICIARIES, CREATING A BUDGETARY SHORTFALL. AS ONE OF NORTHEAST OHIO'S TOP PROVIDERS OF HOSPITAL CARE FOR MEDICAID PATIENTS, SUMMA HEALTH'S UNPAID COSTS FOR MEDICAID TOTALED MORE THAN \$40 MILLION. BAD DEBT SUMMA HEALTH IS COMMITTED TO PROVIDING QUALITY AND ACCESSIBLE HEALTHCARE. THIS INCLUDES COVERING THE EXPENSE OF PAYMENTS THAT WERE EXPECTED BUT NOT RECEIVED. WHILE SUMMA HEALTH RECOGNIZES BAD DEBT IS PART OF DOING BUSINESS, IT AGREES WITH THE OHIO HOSPITAL ASSOCIATION THAT IT IS IMPORTANT TO REPORT THESE COSTS TO SHOW THE TOTAL PICTURE OF CARE SUMMA HEALTH PROVIDES TO THE COMMUNITY WITHOUT FULL REIMBURSEMENT. IN 2017, THE COST FOR PROVIDING CARE WRITTEN OFF AS A BAD DEBT EXPENSE WAS APPROXIMATELY \$15.4 MILLION. COMMUNITY HEALTH IMPROVEMENT SERVICES AN IMPORTANT PART OF SUMMA HEALTH'S MISSION IS OFFERING A PREVENTION AND WELLNESS PROGRAM TO BUILD A HEALTHIER COMMUNITY. IN 2017, SUMMA

HEALTH PROVIDED MORE THAN \$8.1 MILLION TO HELP FUND HEALTH IMPROVEMENT

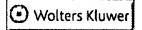
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Schedule O (Form 990 or 990-EZ) (2017) Page 2 **Employer identification number** Name of the organization SUMMA HEALTH GROUP RETURN 90-0640432 USING A SLIDING SCALE BASED ON THE FEDERAL POVERTY INCOME GUIDELINES TO DETERMINE THE CHARITY DISCOUNT FOR WHICH THE PATIENT MAY BE ELIGIBLE. IN 2017, SUMMA HEALTH PROVIDED CHARITY CARE TO THE INDIGENT (INCLUDING UNREIMBURSED MEDICAID) AT THE COST OF APPROXIMATELY \$33 MILLION. THIS AMOUNT DOES NOT INCLUDE SERVICES PROVIDED WRITTEN OFF AS BAD DEBT. IN ADDITION TO UNCOMPENSATED MEDICAL CARE, SUMMA HEALTH PROVIDED WELLNESS PROGRAMS, COMMUNITY EDUCATION PROGRAMS AND SPECIAL PROGRAMS FOR THE ELDERLY, PERSONS WITH DISABILITIES AND THE MEDICALLY SUMMA HEALTH ALSO OPERATED A VARIETY OF BROAD COMMUNITY SUPPORT ACTIVITIES. THESE PROGRAMS WERE OFFERED AT A REDUCED PRICE OR PROVIDED TO THE COMMUNITY FREE OF CHARGE. SUMMA HEALTH OPERATES ITS FACILITIES IN A MANNER CONSISTENT WITH THE COMMUNITY BENEFIT REQUIREMENTS OF REV. RULE 69-545 AND SUBSEQUENT CASE LAW AND IRS GUIDELINES. SUMMA HEALTH'S HOSPITALS PROVIDE EMERGENCY SERVICES WHICH ARE OPEN AND AVAILABLE TO ALL PERSONS OF THE COMMUNITY, REGARDLESS OF THEIR ABILITY TO PAY. THE BOARD OF DIRECTORS CONSISTS OF PERSONS WHO ARE BROADLY REPRESENTATIVE OF THE COMMUNITY AND MEDICAL STAFF. SUMMA HEALTH MEDICAL GROUP- PROGRAM SERVICE ACCOMPLISHMENTS: SUMMA HEALTH MEDICAL GROUP, A SUMMA HEALTH ENTITY, IS A MULTI-SPECIALTY GROUP OF PHYSICIANS AND PHYSICIAN PRACTICES. IN TOTAL, SUMMA HEALTH MEDICAL GROUP EMPLOYS NEARLY 300 PHYSICIANS AND MORE THAN 700 SUPPORT STAFF IN MORE THAN 30 SPECIALTIES AND SUB-SPECIALTIES. SUMMA HEALTH MEDICAL GROUP PROMOTES STRONG AFFILIATION AND EMPLOYMENT OF PHYSICIANS

Format: Abstract -

Full text links

Page 94 of 201



J Am Acad Orthop Surg. 1999 Jul-Aug;7(4):262-9.

Muscle strain injury: diagnosis and treatment.

Noonan TJ¹, Garrett WE Jr.

Author information

Abstract

Muscle strain is a very common injury. Muscles that are frequently involved cross two joints, act mainly in an eccentric fashion, and contain a high percentage of fast-twitch fibers. Muscle strain usually causes acute pain and occurs during strenuous activity. In most cases, the diagnosis can be made on the basis of the history and physical examination. Magnetic resonance imaging is recommended only when radiologic evaluation is necessary for diagnosis. Initial treatment consists of rest, ice, compression, and nonsteroidal anti-inflammatory drug therapy. As pain and swelling subside, physical therapy should be initiated to restore flexibility and strength. Avoiding excessive fatigue and performing adequate warm-up before intense exercise may help to prevent muscle strain injury. The long-term outcome after muscle strain injury is usually excellent, and complications are few.

PMID: 10434080

[Indexed for MEDLINE]

Publication type, MeSH terms, Substance

Publication type

Review

MeSH terms

Anti-Inflammatory Agents, Non-Steroidal/therapeutic use

Combined Modality Therapy

<u>Humans</u>

Muscle, Skeletal/injuries*

Muscle, Skeletal/pathology

Physical Therapy Modalities



CV-2016-09-3928 MICHAEL, KATHRYN 05/15/2019 20:51:50 PM NFIL Page 95 of 201

Risk Factors

Rupture

Sprains and Strains/diagnosis

Sprains and Strains/etiology

Sprains and Strains/rehabilitation*

Substance

Anti-Inflammatory Agents, Non-Steroidal

LinkOut - more resources

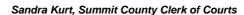
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PMID: <u>24977084</u>

Treatment of Skeletal Muscle Injury: A Review

L. Baoge, ¹ E. Van Den Steen, ² S. Rimbaut, ² N. Philips, ² E. Witvrouw, ³ K. F. Almqvist, ⁴ G. Vanderstraeten, ², ³ and L. C. Vanden Bossche ², ^{*}

¹Beijing Tiantan Hospital, Capital Medical University, Beijing Tiantan Xili 6, Beijing 100050, China

*L. C. Vanden Bossche: <u>luc.vandenbossche@ugent.be</u>

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Abstract

Skeletal muscle injuries are the most common sports-related injuries and present a challenge in primary care and sports medicine. Most types of muscle injuries would follow three stages: the acute inflammatory and degenerative phase, the repair phase and the remodeling phase. Present conservative treatment includes RICE (rest, ice, compression, elevation), nonsteroidal anti-inflammatory drugs (NSAIDs) and physical therapy. However, if use improper, NSAIDs may suppress an essential inflammatory phase in the healing of injured skeletal muscle. Furthermore, it remains controversial whether or not they have adverse effects on the healing process or on the tensile strength. However, several growth factors might promote the regeneration of injured skeletal muscle, many novel treatments have involved on enhancing complete functional recovery. Exogenous growth factors have been shown to regulate satellite cell proliferation, differentiation and fusion in myotubes in vivo and in vitro, $TGF-\beta I$ antagonists behave as inhibitors of $TGF-\beta I$. They prevent collagen deposition and block formation of muscle fibrosis, so that a complete functional recovery can be achieved.

1. Introduction

Skeletal muscle injuries are the most common sports-related injuries and present a challenge in primary care and sports medicine. Athletes sustain muscle injuries through a variety of mechanisms, including direct trauma (e.g., lacerations, strains, and contusions) and indirect injuries (related to ischemia and neurological dysfunctions).

²Department of Physical and Rehabilitation Medicine, Ghent University Hospital, 9000 Ghent, Belgium

³Department of Rehabilitation Sciences and Physiotherapy, Ghent University, 9000 Ghent, Belgium

⁴Department of Orthopaedic Surgery and Traumatology, Ghent University Hospital, 9000 Ghent, Belgium

A regeneration process that is similar in most types of muscle injuries, has been observed. However, complete recovery from the injury is compromised due to the development of fibrosis in the second week after the injury. The formed scar tissue always is mechanically inferior and therefore much less able to perform the functions of a normal muscle fiber. It is also more susceptible to reinjury [1, 2]. To minimize the disability and enhance full functional recovery after skeletal muscle injuries, the current conservative treatment includes limiting the bleeding with compression, elevation, and local cooling, nonsteroidal anti-inflammatory drugs (NSAIDs), and physical therapy [3].

Recently, it has been suggested that growth factors might promote the regeneration of injured skeletal muscle, and many novel treatments have been developed.

This review paper focuses on the rapeutic approaches including new knowledge of routine NSAIDs. novel biological repair, and physical therapy. A search of the literature on the treatment of skeletal muscle injuries was conducted using PubMed and Medscape.

2. The Pathological Process Following Muscle Injury

The general injury and repair mechanism is similar in most types of muscle injuries. Three stages are distinguished: the destruction and inflammatory phase (1 to 3 days), the repair phase (3 to 4 weeks), and the remodeling phase (3 to 6 months) [4, 5]. The last two phases tend to overlap.

When a muscle is injured, the myofibers rupture and necrotize. A haematoma is formed. At the same time during this first phase, the inflammatory cells can freely invade the injury site because the blood vessels are torn. The most abundant inflammatory cells are the polymorphonuclear leukocytes. These are replaced by monocytes, a few hours after the injury. These cells eventually transform into macrophages. Macrophages have 2 functions. Firstly, they remove the necrotic myofibers by phagocytosis. Secondly, they produce, together with fibroblasts, chemotactic signals such as growth factors, cytokines, and chemokines. The extracellular matrix (ECM) also contains growth factors that become active when tissue is damaged. Some of these growth factors, such as FGF (fibroblast growth factor), IGF-1 (insulin-like growth factor-1), IGF-2 (insulin-like growth factor-2), TGF-β (transforming growth factor- β), HGF (hepatocyte growth factor), TNF- α (tumor necrosis factor- α), and IL-6 (interleukin-6) can activate myogenic precursors, called the satellite cell [3, 6, 7].

The next phase, the repair phase, consists of 2 concomitant processes. The first is the regeneration of the disrupted myofibers. Regeneration can occur because there still is a pool of undifferentiated reserve cells, also called myogenic precursors or satellite cells under the basal lamina of the myofiber. The satellite cells will proliferate and eventually differentiate into myoblasts. Because these new myoblasts fuse with the injured myofibers, the gap formed between the two ends of the injured myofiber is refilled. The second process of the repair phase is the formation of a connective tissue scar by fibrin and fibronectin, derived from blood of the haematoma that was formed immediately after the injury. The scar tissue gives the muscle strength to withstand contractions, and it gives the fibroblasts an anchoring site to invade the granulation tissue. However, in case of excessive proliferation of these fibroblasts, dense scar tissue is formed within the injured muscle. This not only interferes with the repair process but also interrupts the muscle regenerative process and contributes to incomplete functional recovery of the injured muscle during the third phase, the remodeling phase. In this last phase, the newly formed myofibers mature. At the same time, the scar tissue is reorganized and it contracts [3, 6, 7].

Due to an injury, the intramuscular nerve branches can be damaged. Hence, the muscle fibers may be denervated, which might affect the healing process negatively [8].

The whole process is coordinated through different mechanisms like cell-cell and cell-matrix interactions as well as extracellular secreted factors. HGF, IL-1, and IL-6 are secreted factors that can stimulate the activity of satellite cells. FGF and IGF can also activate satellite cells, but in contrast to IGF, FGF can also inhibit their differentiation, while IGF stimulates the differentiation. TGF-β1 stimulates collagen deposition, leading to the formation of fibrotic scar tissue [9–13].

3. Therapeutic Strategies

MICHAEL. KATHRYN

A variety of conservative treatment strategies exist for acute and chronic skeletal muscle injuries [14]. 15]. The primary treatment goals are to minimize further damage, relieve pain and spasm, reduce haemorrhage and edema, and promote healing. Furthermore, the recurrent nature of muscle injuries often requires a functional approach from the acute phase to the final goal of return to sports.

4. RICE

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The best known treatment immediately after a muscle injury is the "RICE approach". This acronym stands for rest, ice, compression and elevation. The aim is to minimize the haematoma of the injured muscle and, subsequently, the size of the connective tissue scar. However, the effectiveness of this approach has not been proven in any randomized clinical trial [3]. Ice should be applied intermittently for 15 to 20 minutes with an interval of 30 to 60 minutes. Longer periods of cold application lead to increased circulation and increased bleeding [8].

Physiotherapy

Early mobilization accelerates capillary ingrowth and promotes the regeneration of muscle fibers. The healed muscle also more rapidly regains its preinjury level of strength. However, early mobilization also has disadvantages. The scar that is formed will be larger, and reruptures will be more common. Therefore, rest is advised during the first 3 to 7 days to allow the scar tissue to gain strength. Subsequently, mobilization within the painfree limits is initiated. Continued inactivity can lead to atrophy of the healthy muscles, excessive deposition of connective tissue within the muscles and a substantially retarded recovery of the strength of the injured skeletal muscle. Exercises should be started gradually. Isometric training should be followed by isotonic training and isotonic training by isokinetic training once the respective exercises can be performed without pain [3].

6. NSAIDs

NSAIDs are primarily used for their analgesic, anti-inflammatory, and antipyretic properties [16]. Inflammatory cells play an important role in the healing process of an injured muscle. Therefore, the use of drugs that inhibit these cells, such as NSAIDs, is questioned nowadays. Experimental studies in which NSAIDs were given immediately after the injury, have shown conflicting results. NSAIDs would not have a greater effect on the pain of a muscle injury than paracetamol, but they have more side effects including asthma exacerbations, gastrointestinal and renal side effects, hypertension, and other. However, NSAIDs also have beneficial effects. The inflammatory process can be excessive and cause edema, resulting in anoxia and further cell death. This can be prevented by the administration of low-dose NSAIDs [17].

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Rahusen et al. reviewed earlier reports on the use of NSAIDs to clarify recommendations for their use [18]. Basically, NSAIDs should be given no sooner than 48 hours following exercise-induced muscle injuries to provide analgesia and to reduce the early inflammatory response. Earlier use can interfere with the cell chemotaxis that is necessary for the repair and remodeling of regenerating muscle. In the 2 days after the injury, paracetamol can be used for analgesia. Prolonged use of NSAIDs (over 7 days) is not recommended as it would delay muscle regeneration by inactivating the proliferation and differentiation of satellite cells and inhibiting the production of growth factors [18, 19].

It would also reduce the biomechanical strength of the injured muscle and delay elimination of the haematoma and the necrotic tissue [20]. In contrast with the findings of these authors, Engelberg et al. and Almekinders [21] showed no significant effect on tensile strength recovery following NSAID treatment for muscle strain injury. Engelberg et al. further demonstrated that muscle strength also remained unaltered [22].

7. Biological Repair

Recently, several studies have led to the identification of growth factors that have the potential to influence the regeneration of injured muscles. Since then, multiple research groups have been trying to find drugs that work on this natural basis and can help an injured muscle to recover better and/or faster [12, 23, 24] (Figure 1). To achieve this goal, the researchers investigated several biological growth factors, such as exogenous growth factors which would promote healing of injured muscle fibers, and $TGF-\beta 1$, the inhibition of which would block the muscle fibrosis (Table 1).

Open in a separate window

Figure 1

Autologous platelet tissue graft: mechanism of action.

Table 1

Effect of growth factors in musculoskeletal tissues.

Open in a separate window

*Positive effect; "no or negative effect; blank: not tested; IGF-1: insulin-like growth factor-1; bFGF: basic fibroblast growth factor; NGF: nerve growth factor; PDGF: platelet-derived growth factor; EGF: epidermal growth factor; TGF: transforming growth factor; BMP-2: bone morphogenetic protein-2.

Several growth factors are capable of promoting muscle regeneration [13, 25]. These include basic fibroblast growth factor (bFGF), insulin growth factor (IGF), nerve growth factor (NGF), TGF- β 1, and platelet-derived growth factor (PDGF). Mitchell et al. reported that the short biologic half-life of

l Çi administered bFGF may limit its stimulatory effect on satellite cells [26]. They coinjected bFGF with heparin and used sustained release polymers without success. Conversely, Armand et al. found that the direct delivery of recombinant bFGF-6 into the site of injury can accelerate the regeneration of the soleus muscle in adult mice by stimulating the differentiation process of the myotubes [27].

Takahashi et al. observed that gene delivery of IGF-1 via electroporation resulted in an increased number of regenerating myofibers by 2 weeks after injury and in an increased regenerating myofiber size by 4 weeks after injury [28]. Huard et al. injected IGF in healthy old men, thus preventing the loss of muscle mass that is typical of aging. However, IGF-injection has side effects in that it promotes the development of fibrosis by stimulating the production of matrix components such as collagen and decreasing the expression of matrix-degrading enzymes such as collagenase [29]. In a mice model of muscle strain, Kasemkijwattana et al. evaluated the ability of bFGF, NGF and IGF-1 to promote muscle regeneration in vivo by three repeated injections of 100 ng into the injury site 1, 3, and 5 days after the injury [30]. In this study, physiologic strength testing was correlated with histologic analysis of the treated and nontreated muscles; the number and diameter of regenerating myofibers were monitored as an index of muscle regeneration. Their data indicated that bFGF and IGF-1, properly applied, can improve muscle performance after a strain injury. Throughout this study, growth factors had been injected on only 1 to 3 and 5 days after injury, resulting in an improvement of the tetanic and fasttwitch strength of the treated muscle, when compared with sham-injected strain-injured muscle. In addition, NGF was found capable of enhancing fast-twitch strength, but the titanic strength was not significantly different between the treated and nontreated muscle [30].

Miller et al. postulated that local delivery of HGF would augment satellite cell activation in regenerating muscle, and that this increased number of myogenic precursor cells would lead to an enhancement of muscle repair. Their study showed that, when HGF was injected in injured muscles, the number of myoblasts increased, but this increase did not lead to a better regeneration of the injected muscle. Instead, when HGF was injected the first 4 days after injury, muscle regeneration was inhibited. When it was administered later, the injection had no effect. Miller et al. also found that HGF had a dose-dependent effect on the number of myoblasts in regenerating muscles [31]. Two different doses of HGF, 6.25 and 50 ng, were used in this study. Treatment with 6.25 ng HGF did not significantly increase the number of myoblasts compared with control at any time tested. In contrast, muscles treated with 50 ng HGF on the day of injury and analyzed 1 day later yielded about threefold more MyoD-positive cells than did control muscles. In muscles further treated with HGF on subsequent days and analyzed either 2 or 3 days after injury, no significantly increased number of myoblasts was observed. This study demonstrated the effects of exogenous HGF administration on satellite cell activation and differentiation in regenerating mouse muscles after trauma. It showed the dual role HGF plays in regulating satellite cell activation and differentiation [31].

Kasemkijwattana and Menetrey et al. observed that b-FGF, IGF-1, and NGF are potent stimulators of the proliferation and fusion of myoblasts in vivo [1, 30, 32]. These growth factors were injected into mice with lacerations of the gastrocnemius muscle. Muscle regeneration was evaluated at 1 week by histological staining and quantitative histology. Muscle healing was assessed histologically and the contractile properties were measured 1 month after injury. In the treated group, the number of regenerating myofibers was increased 3.5 times for bGF and IGF-1 and 1.5 times for NGF. Those data suggested that specific growth factors were able to improve regeneration of injured muscle by stimulating myogenic proliferation and differentiation.

As discussed above, regeneration of an injured muscle consists of 2 elements. First, there needs to be proliferation and differentiation of myoblasts. This is promoted by growth factors (Table 1). Secondly, scar tissue has to be minimal. Many studies indicate that the overproduction of TGF- β 1 is responsible for the tissue fibrosis both in animals and humans [33]. Therefore, researchers have also tried to develop drugs that inhibit TGF- β 1. Chan et al. used the TFG- β 1 antagonist suramin in their study. Suramin is an antiparasitic and antitumor drug that competitively binds to the TGF-\(\beta\)1 receptor. When suramin was injected immediately or 7 days after the injury, it had only a minor effect on muscle fibrosis. However, when a high dose of suramin was injected 14 days after injury, it prevented fibrosis more effectively than did a lower concentration or no suramin. There were more regenerating myofibers in all the suramin-treated groups than in the control groups. Just as the prevention of fibrosis, the number of regenerating myofibers was dose dependent. Side effects of suramin are adrenocortical insufficiency, malaise, neuropathy, and corneal deposits. Occasionally, neutropenia, thrombocytopenia, and renal failure may occur. However, the toxicity of suramin delivered via intramuscular injection has not yet been determined. In the study, no side effects were encountered [33]. These results are consistent with those of Nozaki et al. who injected 2.5 mg of suramin 2 weeks after contusion. They also found less fibrosis and better healing of the muscle. Once healed, the injected muscle was also stronger than the control muscles. A dose-response effect was not observed [<u>34</u>].

Decorin also inactivates the effect of TGF- β 1. Fukushima et al. found that the injection of decorin at 10 and 15 days after injury significantly decreased the amount of fibrosis. Decorin had the additional advantage of enhancing the regeneration of the injured muscle. There seemed to be a dose-response effect. No side effects were observed [$\underline{\delta}$].

8. Operative Treatment

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Menetrey et al. used a muscle laceration model developed in mice to investigate whether surgery is a better technique to accelerate recovery of a muscle injury than immobilization. At 2 days after the laceration, the mice that had surgery only had a superficially located minor haematoma, while the immobilized mice had a larger and deeper haematoma. At the end, the immobilized mice had more and deeper scar tissue than the sutured mice. The functional results of surgery were also superior to those of immobilization [35].

Surgery can only be implemented in specific conditions. These include a large intramuscular haematoma, a complete strain or tear of a muscle with few or no agonist muscles or a partial strain if more than half of the muscle belly is torn and if the patient complains of persistent (>4–6 months) extension pain. After surgery, the operated limb should be placed in a cast and immobilized in a neutral position with an orthosis.

9. Discussion

When a skeletal muscle is injured, satellite cells are activated by a variety of growth factors within 18 hours of injury, as a result of a response to a chemical stimulus [5, 36, 37]. At the same time, inflammatory cells migrate to the injury site from healthy areas of the muscle. Regeneration of single muscle fibers or entire muscles can only occur when satellite cells are activated. The optimal treatment for these muscle injuries remains obscure in routine clinical practice.

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The RICE approach is generally used in the acute stage. The value of this treatment is not fully known, but most authors consider it as not harmful and maybe helpful to limit the bleeding in the muscles. It consists of rest, ice, compression, and elevation [3]. During the first 7 days after a muscle injury, rest should be taken, so that the scar tissue can gain strength. Afterwards, physiotherapy can be started [3].

Whether or not NSAIDs should be used in the treatment of muscle injuries is still controversial. They have long been the first choice to relieve pain after a skeletal muscle injury. NSAIDs may suppress the inflammatory response and thus reduce the pain and swelling. However, this response is an essential phase in the healing of injured skeletal muscle. Attempts to inhibit this phase will lead to an incomplete functional recovery. NSAIDs could interfere with macrophage action, limit phagocytic function, and impede production of growth-promoting factors that are responsible for regeneration after muscle injury. Experimental investigations showed that NSAIDs might also decrease the tensile strength of the injured muscle. Delayed muscle regeneration has been observed in treated animals [38]. Other studies did not come to this conclusion. Therefore, the exact role of NSAIDs should be established in animal models and in controlled clinical studies of skeletal muscle injuries. Until then, most authors advise that NSAIDs should not be given the first 48 hours after the injury. If the patient is in pain, paracetamol can be administered for analgesia.

A better understanding of the biological and pathological processes of muscle repair following skeletal muscle injury has led to the use of growth factors.

Growth factors have been shown to regulate satellite cell proliferation, differentiation, and fusion in myotubes in vivo and in vitro. Recently, growth factors have been found to promote the differentiation of myogenic cells in vivo and in vitro and eventually enhance complete functional recovery after muscle injury. Among these growth factors, NGF was the first to be identified and used to promote repair in peripheral and central nervous system injuries [39]. NGF may also be useful in muscle regeneration, especially during the reinnervation phase [40]. Injection of IGF increases the number and the size of regenerating myofibers after muscle injury [41]. Injection of b-FGF showed that this growth factor is a potent stimulator of the proliferation and fusion of myoblasts in vivo and in vitro [42].

TGF- β 1 is a key factor, responsible for the formation of muscle fibrosis during the repair process by stimulating a variety of cells to increase the synthesis of numerous matrix proteins [43]. In response to muscle injury, TGF-\beta1 provides an upregulated immune mechanism which leads to an increased cellular adhesion to the ECM and ultimately enhances myofibroblast survival by inhibiting apoptosis. TGF- β I is expressed at high levels and is associated with massive muscle fibrosis observed in patients with Duchenne muscular dystrophy. Based on this biological rationale of the role of TGF- β 1, several novel researches have focused on the inhibition of TGF- β 1 in muscle healing.

TGF- β 1 antagonists behave as inhibitors of TGF- β 1 by binding to its receptor and blocking its actions, in order to prevent collagen deposition and to block formation of muscle fibrosis. Among these antifibrotic agents, decorin and suramin have been demonstrated to block fibrosis and promote functional recovery of injured skeletal muscle. Decorin binds to TGF- β 1 in order to counteract its action and suramin competitively binds to the TGF- β 1 receptor that inhibits TGF- β expression [44]. However, the side effects of growth hormone factors must be taken into account, edema, and arthralgia or myalgia being most common in adults [45].

Surgery should be preserved for special cases as mentioned before. If symptoms fail to improve, the possibility of intramuscular haematoma and tissue damage should be reconsidered. Measurement of intramuscular pressure, soft-tissue X-rays, or ultrasound examination may be required [8].

Authors' Recommendations

After a muscle injury, the RICE principle should be implemented immediately. Seven days of rest are advised, after which physiotherapy should be started. NSAIDs can be used after 48 hours. The rationale for using NSAIDs in these conditions is based on their anti-inflammatory properties. Inflammation is an essential component of the healing process. Therefore, the appropriate timing of NSAID administration may play a key role in the therapeutic approach to skeletal muscle injuries [46]. In the future, the routine use of NSAIDs in muscle injuries should be further critically evaluated and compared with other treatment strategies in prospective randomized controlled trials.

The use of growth factors, particularly bFGF, NGF, and IGF-I, is a novel therapeutic approach to promote full functional recovery after muscle injuries. Autologous growth factors might induce myogenic proliferation, stimulate differentiation, and as such accelerate the healing of inflamed and injured muscle. Inhibition of TGF- β 1 expression contributes to the blocking of muscle fibrosis in order to minimize the formation of fibrous scar tissue and to promote the restoration of functional muscle fibers within the injured site.

A treatment that enhances the repair of injured muscle could have significant clinical applications [47]. Therefore, further studies must be conducted to evaluate the safety of using growth factors and antifibrotic agents. Future research should focus on the use of growth factors that facilitate muscle regeneration in vivo. The balance between growth and differentiation must be maintained in order to restore functional muscle structure and to identify the different roles of the various growth factors.

Their clinical application in skeletal muscle injuries should be optimized and even combined with new techniques such as gene therapy and tissue engineering, not merely based on experimental studies or empirical evidence.

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CLINICAL GUIDELINES | 4 APRIL 2017

Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians

Article, Author, and Disclosure Information

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Description: The American College of Physicians (ACP) developed this guideline to present the evidence and provide clinical recommendations on noninvasive treatment of low back pain.

Methods: Using the ACP grading system, the committee based these recommendations on a systematic review of randomized, controlled trials and systematic reviews published through April 2015 on noninvasive pharmacologic and nonpharmacologic treatments for low back pain. Updated searches were performed through November 2016. Clinical outcomes evaluated included reduction or elimination of low back pain, improvement in back–specific and overall function, improvement in health–related quality of life, reduction in work disability and return to work, global improvement, number of back pain episodes or time between episodes, patient satisfaction, and adverse effects.

Target Audience and Patient Population: The target audience for this guideline includes all clinicians, and the target patient population includes adults with acute, subacute, or chronic low back pain.

PLAINTIFF'S
EXHIBIT

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Recommendation 1: Given that most patients with acute or subacute low back pain improve over time regardless of treatment, clinicians and patients should select nonpharmacologic treatment with superficial heat (moderate-quality evidence), massage, acupuncture, or spinal manipulation (low-quality evidence). If pharmacologic treatment is desired, clinicians and patients should select nonsteroidal anti-inflammatory drugs or skeletal muscle relaxants (moderate-quality evidence). (Grade: strong recommendation)

Recommendation 2: For patients with chronic low back pain, clinicians and patients should initially select nonpharmacologic treatment with exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction (moderate-quality evidence), tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, or spinal manipulation (low-quality evidence). (Grade: strong recommendation)

Recommendation 3: In patients with chronic low back pain who have had an inadequate response to nonpharmacologic therapy, clinicians and patients should consider pharmacologic treatment with nonsteroidal anti-inflammatory drugs as first-line therapy, or tramadol or duloxetine as second-line therapy. Clinicians should only consider opioids as an option in patients who have failed the aforementioned treatments and only if the potential benefits outweigh the risks for individual patients and after a discussion of known risks and realistic benefits with patients. (Grade: weak recommendation, moderate-quality evidence)

Low back pain is one of the most common reasons for physician visits in the United States. Most Americans have experienced low back pain, and approximately one quarter of U.S. adults reported having low back pain lasting at least 1 day in the past 3 months (1). Low back pain is associated with high costs, including those related to health care and indirect costs from missed work or reduced productivity (2). The total costs attributable to low back pain in the United States were estimated at \$100 billion in 2006, two thirds of which were indirect costs of lost wages and productivity (3).

Low back pain is frequently classified and treated on the basis of symptom duration,

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potential cause, presence or absence of radicular symptoms, and corresponding anatomical or radiographic abnormalities. Acute back pain is defined as lasting less than 4 weeks, subacute back pain lasts 4 to 12 weeks, and chronic back pain lasts more than 12 weeks. Radicular low back pain results in lower extremity pain, paresthesia, and/or weakness and is a result of nerve root impingement. Most patients with acute back pain have self-limited episodes that resolve on their own; many do not seek medical care (4). For patients who do seek medical care, pain, disability, and return to work typically improve rapidly in the first month (5). However, up to one third of patients report persistent back pain of at least moderate intensity 1 year after an acute episode, and 1 in 5 report substantial limitations in activity (6). Many noninvasive treatment options are available for radicular and nonradicular low back pain, including pharmacologic and nonpharmacologic interventions.

Guideline Focus and Target Population

The purpose of this American College of Physicians (ACP) guideline is to provide treatment guidance based on the efficacy, comparative effectiveness, and safety of noninvasive pharmacologic and nonpharmacologic treatments for acute (<4 weeks), subacute (4 to 12 weeks), and chronic (>12 weeks) low back pain in primary care. This guideline does not address topical pharmacologic therapies or epidural injection therapies. It serves as a partial update of the 2007 ACP guideline (it excludes evidence on diagnosis). These recommendations are based on 2 background evidence reviews (7, 8) and a systematic review sponsored by the Agency for Healthcare Research and Quality (AHRQ) (9). The target audience for this guideline includes all clinicians, and the target patient population includes adults with acute, subacute, or chronic low back pain.

Methods

Systematic Review of the Evidence

The evidence review was conducted by the AHRQ's Pacific Northwest Evidence-based Practice Center. Additional methodological details can be found in the Appendix as well as in

the accompanying articles (7, 8) and full report (9). Reviewers searched several databases for studies published in English from January 2008 through April 2015 and updated the search through November 2016. Studies published before 2007 were identified using the 2007 ACP/American Pain Society (APS) systematic reviews (10, 11). Reviewers combined data when possible using meta-analysis and assessed risk of bias and study quality according to established methods. The study population included adults (aged ≥18 years) with acute, subacute, or chronic nonradicular low back pain, radicular low back pain, or symptomatic spinal stenosis.

The review evaluated pharmacologic (acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs], opioids, skeletal muscle relaxants [SMRs], benzodiazepines, antidepressants, antiseizure medications, and systemic corticosteroids) and nonpharmacologic (psychological therapies, multidisciplinary rehabilitation, spinal manipulation, acupuncture, massage, exercise and related therapies, and various physical modalities) treatments for low back pain. Evaluated outcomes included reduction or elimination of low back pain, improvement in back-specific and overall function, improvement in health-related quality of life, reduction in work disability, return to work, global improvement, number of back pain episodes or time between episodes, patient satisfaction, and adverse effects.

The magnitude of effect (small, moderate, or large) was determined as previously described (10, 11). A small effect on pain was defined as a mean between-group difference after treatment of 5 to 10 points on a visual analogue scale of 0 to 100 or equivalent, a mean between-group difference of 0.5 to 1.0 point on a numerical rating scale of 0 to 10, or a standardized mean difference of 0.2 to 0.5. A moderate effect was defined as a mean between-group difference of greater than 10 to no more than 20 points on a visual analogue scale of 0 to 100 or equivalent, a mean between-group difference of greater than 1.0 to no more than 2.0 points on a numerical rating scale of 0 to 10 or equivalent, or a standardized mean difference greater than 0.5 but no more than 0.8. For function, a small effect was defined as a mean between-group difference of 5 to 10 points on the Oswestry Disability Index (ODI), a mean between-group difference of 1 to 2 points on the Roland Morris Disability Questionnaire (RDQ), or a standardized mean difference of 0.2 to 0.5. A moderate

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effect on function was defined as a mean between-group difference of greater than 10 to no more than 20 points on the ODI, a mean between-group difference of greater than 2 to no more than 5 points on the RDQ, or a standardized mean difference greater than 0.5 but no more than 0.8. No large effects were found with any intervention.

Grading the Evidence and Developing Recommendations

This guideline was developed by ACP's Clinical Guidelines Committee (CGC) according to ACP's guideline development process, details of which can be found in the methods paper (12). The CGC used the evidence tables in the accompanying evidence reviews (7, 8) and full report (9) when reporting the evidence and graded the recommendations using the ACP's guideline grading system (Table).

Table. The American College of Physicians Guideline Grading System*

Quality of Evidence	Strength of Recommendation		
	Benefits Clearly Outweigh Risks and Burden or Risks and Burden Clearly Outweigh Benefits	Benefits Finely Balenced With Risks and Burden	
High 2	Strong	Wesk	
Moderate	Strong	Weak	
Low	Strong	Wenk	

Peer Review

The AHRQ systematic review was sent to invited peer reviewers and posted on the AHRQ Web site for public comments. The accompanying evidence reviews (7, 8) also underwent a peer review process through the journal. The guideline underwent a peer review process through the journal and was posted online for comments from ACP Regents and ACP Governors, who represent ACP members at the regional level.

Benefits and Comparative Benefits of Pharmacologic Therapies

Acute or Subacute Low Back Pain

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Appendix Table 1 summarizes the findings for all therapies for acute or subacute low back pain.

Appendix Table 1. Pharmacologic and Nonpharmacologic Treatments for Acute or Subacute Low Back Pain



Acetaminophen

Low-quality evidence showed no difference between acetaminophen and placebo for pain intensity or function through 4 weeks or between acetaminophen and NSAIDs for pain intensity or likelihood of experiencing global improvement at 3 weeks or earlier (13, 14).

NSAIDs

Moderate-quality evidence showed that NSAIDs were associated with a small improvement in pain intensity compared with placebo (14, 15), although several randomized, controlled trials (RCTs) showed no difference in likelihood of achieving pain relief with NSAIDs compared with placebo (16–18). Low-quality evidence showed a small increase in function with NSAIDs compared with placebo (19). Moderate-quality evidence showed that most head-to-head trials of one NSAID versus another showed no differences in pain relief in patients with acute low back pain (14). Low-quality evidence showed no differences in pain

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between cyclooxygenase (COX)-2-selective NSAIDs versus traditional NSAIDs (14).

SMRs

Moderate-quality evidence showed that SMRs improved short-term pain relief compared with placebo after 2 to 4 and 5 to 7 days (20, 21). Low-quality evidence showed no differences between different SMRs for any outcomes in patients with acute pain (20). Low-quality evidence showed inconsistent findings for the effect on pain intensity with a combination of SMRs plus NSAIDs compared with NSAIDs alone (20, 22, 23).

Systemic Corticosteroids

Low-quality evidence showed no difference in pain or function between a single intramuscular injection of methylprednisolone or a 5-day course of prednisolone compared with placebo in patients with acute low back pain (24, 25).

Other Therapies

Evidence was insufficient to determine effectiveness of antidepressants, benzodiazepines (26, 27), antiseizure medications, or opioids versus placebo in patients with acute or subacute low back pain.

Chronic Low Back Pain

Appendix Table 2 summarizes the findings for all therapies for chronic low back pain.

Appendix Table 2. Pharmacologic and Nonpharmacologic Treatments for Chronic Low Back Pain

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Appendix Table 2. Continued



NSAIDs

Moderate-quality evidence showed that NSAIDs were associated with small to moderate pain improvement compared with placebo (14, 28, 29). Low-quality evidence showed that NSAIDs

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were associated with no to small improvement in function (28-31). Moderate-quality evidence showed that most head-to-head trials of one NSAID versus another showed no differences in pain relief in patients with chronic low back pain (14). There were no data on COX-2-selective NSAIDs.

Opioids

Moderate-quality evidence showed that strong opioids (tapentadol, morphine, hydromorphone, and oxymorphone) were associated with a small short-term improvement in pain scores (about 1 point on a pain scale of 0 to 10) and function compared with placebo (32–36). Low-quality evidence showed that buprenorphine patches improved short-term pain more than placebo in patients with chronic low back pain; however, the improvement corresponded to less than 1 point on a pain scale of 0 to 10 (37–40). Moderate-quality evidence showed no differences among different long-acting opioids for pain or function (33, 41–44), and low-quality evidence showed no clear differences in pain relief between long-and short-acting opioids (45–50). Moderate-quality evidence showed that tramadol achieved moderate short-term pain relief and a small improvement in function compared with placebo (32, 51, 52).

SMRs

Evidence comparing SMRs versus placebo was insufficient (53–55). Low-quality evidence showed no differences in any outcome between different SMRs for treatment of chronic low back pain (20).

Benzodiazepines

Low-quality evidence showed that tetrazepam improved pain relief at 5 to 7 days and resulted in overall improvement at 10 to 14 days compared with placebo (20).

Antidepressants

Moderate-quality evidence showed no difference in pain between tricyclic antidepressants (TCAs) or selective serotonin reuptake inhibitors (SSRIs) versus placebo, and low-quality evidence showed no differences in function for antidepressants (56). Moderate-quality evidence showed that duloxetine was associated with a small improvement in pain intensity and function compared with placebo (57–59).

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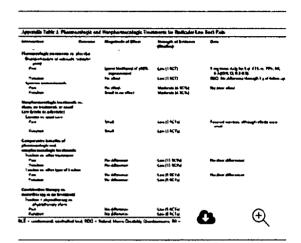
Other Therapies

Evidence was insufficient to determine the effect of acetaminophen, systemic corticosteroids, or antiseizure medications on chronic low back pain.

Radicular Low Back Pain

Appendix Table 3 summarizes the findings for all treatments for radicular low back pain.

Appendix Table 3. Pharmacologic and Nonpharmacologic Treatments for Radicular Low Back Pain



Benzodiazepines

Low-quality evidence showed no difference between diazepam and placebo for function at 1 week through 1 year and analgesic use, return to work, or likelihood of surgery through 1 year of follow-up in patients with acute or subacute radicular pain (60). Diazepam resulted in a lower likelihood of pain improvement at 1 week compared with placebo.

Systemic Corticosteroids

Moderate-quality evidence showed no differences in pain between systemic corticosteroids and placebo and no to small effect on function in patients with radicular low back pain (61–66).

Other Therapies

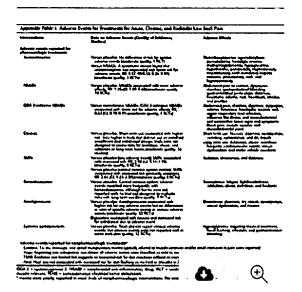
No RCTs evaluated acetaminophen, SMRs, antidepressants, or opioids for radicular low back pain. Results for NSAIDs were inconsistent for pain, and evidence was therefore insufficient (22). There was insufficient evidence to determine the effect of antiseizure medications on radicular low back pain (67-71).

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Harms of Pharmacologic Therapies

Harms were derived from the identified systematic reviews. Adverse effects generally associated with the drugs can be found in Appendix Table 4.

Appendix Table 4. Adverse Events for Treatments for Acute, Chronic, and Radicular Low Back Pain



Moderate-quality evidence showed no difference among scheduled acetaminophen, acetaminophen taken as needed, or placebo for serious adverse events (13). Moderate-quality evidence showed that more adverse effects occurred with NSAIDs than placebo, COX-2selective NSAIDs were associated with a decreased risk for adverse effects compared with traditional NSAIDs, and acetaminophen was associated with a lower risk for adverse effects than NSAIDs (14). Moderate-quality evidence showed that short-term use of opioids increased nausea, dizziness, constipation, vomiting, somnolence, and dry mouth compared with placebo, and SMRs increased risk for any adverse event and central nervous system adverse events (mostly sedation) compared with placebo (20). Moderate-quality evidence showed that antidepressants increased risk for any adverse event compared with placebo, although rates of specific adverse events did not differ (72). The risk for serious adverse events did not differ between duloxetine and placebo, although duloxetine was associated with increased risk for withdrawal due to adverse events (57-59). Low-quality evidence showed no clear differences in adverse effects for gabapentin versus placebo (67, 68). Lowquality evidence showed that benzodiazepines caused more frequent somnolence, fatigue, and lightheadedness than placebo (20). Harms were not well-reported, and no RCTs assessed long-term use of benzodiazepines or risks for addiction, abuse, or overdose. Adverse events

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for systemic corticosteroids were not well-reported in RCTs, but the largest trial found that oral prednisone was associated with increased risk for any adverse event, insomnia, nervousness, and increased appetite (66). However, low-quality evidence showed no cases of hyperglycemia that required medical attention (24, 61, 64).

Comparative Benefits of Nonpharmacologic Therapies

Acute or Subacute Low Back Pain

Exercise

Low-quality evidence showed no difference between exercise therapy and usual care for pain or function in patients with acute or subacute pain (11); additional trials reported inconsistent results (73–75). Moderate-quality evidence showed no clear differences between different exercise regimens in more than 20 head-to-head RCTs in patients with acute low back pain.

Acupuncture

Low-quality evidence showed that acupuncture resulted in a small decrease in pain intensity compared with sham acupuncture with nonpenetrating needles, but there were no clear effects on function (76-78). Low-quality evidence showed that acupuncture slightly increased the likelihood of overall improvement compared with NSAIDs (76, 79-83).

Massage

Low-quality evidence showed that massage moderately improved short-term (1 week) pain and function compared with sham therapy for subacute low back pain (84), although 1 trial (85) showed no difference in pain or function at 5 weeks. Moderate-quality evidence showed that massage improved short-term pain relief and function compared with other interventions (manipulation, exercise therapy, relaxation therapy, acupuncture, or physiotherapy) for patients with subacute to chronic low back pain, but effects were small (84, 86). Low-quality evidence showed that a combination of massage plus another intervention (exercise, exercise and education, or usual care) was superior to the other intervention alone for short-term pain in patients with subacute to chronic low back pain

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(84).

Spinal Manipulation

Low-quality evidence showed that spinal manipulation was associated with a small effect on function compared with sham manipulation; evidence was insufficient to determine the effect on pain (87, 88). Low-quality evidence showed no difference in pain relief at 1 week between spinal manipulation and inert treatment (educational booklet, detuned ultrasound, detuned or actual short-wave diathermy, antiedema gel, or bed rest), although 1 trial showed better longer-term pain relief (3 months) with spinal manipulation (89). Function did not differ between spinal manipulation and inert treatment at 1 week or 3 months (89). Moderate-quality evidence showed no difference between spinal manipulation and other active interventions for pain relief at 1 week through 1 year or function (analyses included exercise, physical therapy, or back school as the comparator) (89, 90). Low-quality evidence showed that a combination of spinal manipulation plus exercise or advice slightly improved function at 1 week compared with exercise or advice alone, but these differences were not present at 1 or 3 months (89).

Superficial Heat

Moderate-quality evidence showed that a heat wrap moderately improved pain relief (at 5 days) and disability (at 4 days) compared with placebo (91). Low-quality evidence showed that a combination of heat plus exercise provided greater pain relief and improved RDQ scores at 7 days compared with exercise alone in patients with acute pain (92). Low-quality evidence showed that a heat wrap provided more effective pain relief and improved RDQ scores compared with acetaminophen or ibuprofen after 1 to 2 days (93). Low-quality evidence showed no clear differences between a heat wrap and exercise in pain relief or function (92).

Low-Level Laser Therapy

Low-quality evidence showed that a combination of low-level laser therapy (LLLT) and NSAIDs largely decreased pain intensity and resulted in a moderate improvement in function (as measured by the ODI) compared with sham laser therapy plus NSAIDs in patients with acute or subacute pain (94).

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Lumbar Supports

Low-quality evidence showed no difference in pain or function between lumbar supports added to an educational program compared with an educational program alone or other active interventions in patients with acute or subacute low back pain (95).

Other Therapies

Evidence was insufficient to determine the effectiveness of transcutaneous electrical nerve stimulation (TENS), electrical muscle stimulation, inferential therapy, short-wave diathermy, traction, superficial cold, motor control exercise (MCE), Pilates, tai chi, yoga, psychological therapies, multidisciplinary rehabilitation, ultrasound, and taping.

Chronic Low Back Pain

Exercise

Moderate-quality evidence showed that exercise resulted in a small improvement in pain relief and function compared with no exercise (11, 96). Moderate-quality evidence showed that compared with usual care, exercise resulted in small improvements in pain intensity and function at the end of treatment, although effects were smaller at long-term follow-up (96). Moderate-quality evidence showed no clear differences between different exercise regimens in more than 20 head-to-head RCTs in patients with chronic low back pain.

MCE

Motor control exercise focuses on restoring coordination, control, and strength of the muscles that control and support the spine. Low-quality evidence showed that MCE moderately decreased pain scores and slightly improved function in short- to long-term follow-up compared with a minimal intervention (97). Low-quality evidence showed that MCE resulted in small improvements in pain intensity at short-term (≥6 weeks to <4 months) and intermediate-term (≥4 to <8 months) follow-up compared with general exercise, although improvements were small and no longer significant at long-term follow-up (97). Motor control exercise also resulted in small improvements in function in the short and long term (97). Low-quality evidence showed that MCE resulted in a moderate improvement in pain intensity and function compared with multimodal physical therapy at intermediate follow-up (97). Low-quality evidence showed no clear differences in pain with

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a combination of MCE plus exercise versus exercise alone (98, 99).

Pilates

Low-quality evidence showed that Pilates resulted in small or no clear effects on pain and no clear effects on function compared with usual care plus physical activity (100–107). Low-quality evidence showed no clear differences between Pilates and other types of exercise for pain or function (108–110).

Tai Chi

Low-quality evidence showed that tai chi resulted in moderate pain improvement compared with wait-list controls or no tai chi (111, 112), and 1 study showed a small increase in function (111). Moderate-quality evidence showed that tai chi moderately decreased pain intensity at 3 and 6 months compared with backward walking or jogging but not versus swimming (112).

Yoga

Low-quality evidence showed that Iyengar yoga resulted in moderately lower pain scores and improved function compared with usual care at 24 weeks (113). Low-quality evidence showed that yoga resulted in a small decrease in pain intensity compared with exercise (114−118). Low-quality evidence showed that, compared with education, yoga resulted in a small decrease in short-term (≤12 weeks) but not long-term (about 1 year) pain intensity and a small increase in short- and long-term function (119).

Psychological Therapies

Low-quality evidence showed that progressive relaxation therapy moderately improved pain intensity and functional status compared with wait-list controls (120). Low-quality evidence showed that electromyography biofeedback training moderately decreased pain intensity (reduction of 5 to 13 points on a 100-point pain scale) compared with wait-list controls, but there was no effect on function (120). Low-quality evidence showed that operant therapy (behavioral therapy involving reinforcement) slightly improved pain intensity compared with wait-list control, although there was no difference for function (120). Low-quality evidence showed that cognitive behavioral therapy (CBT) and other combined psychological therapies (involving education, problem-solving training, coping techniques, imagery, relaxation, goal setting, cognitive pain control, and exercises) were associated with

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moderately improved pain intensity compared with wait-list controls, but there was no difference in function (120). Moderate-quality evidence showed that mindfulness-based stress reduction is an effective treatment for chronic low back pain. One study showed a small improvement in pain at 26 and 52 weeks and in function at 26 weeks compared with usual care (121). The same study showed no difference between mindfulness-based stress reduction and CBT for improvements in pain or function. Two other studies showed improvement in pain and function compared with education (122, 123). Low-quality evidence showed no difference between psychological therapies and exercise or physical therapy for pain intensity (120). Low-quality evidence showed no differences in pain or function between a combination of psychological therapy plus exercise or physiotherapy compared with exercise or physiotherapy alone (120). Moderate-quality evidence showed no differences between different psychological therapies for pain or function outcomes (120).

Multidisciplinary Rehabilitation

Moderate-quality evidence showed that multidisciplinary rehabilitation moderately reduced short-term (<3 months) and slightly reduced long-term pain intensity and disability compared with usual care, although there was no difference in return to work (124). Low-quality evidence showed that multidisciplinary rehabilitation was associated with moderately lower short-term pain intensity and slightly lower disability than no rehabilitation (124). Moderate-quality evidence showed that multidisciplinary rehabilitation was associated with slightly lower short-term pain intensity and disability, moderately lower long-term pain intensity, and improved function compared with physical therapy and a greater likelihood of returning to work compared with nonmultidisciplinary rehabilitation (124).

Acupuncture

Low-quality evidence showed that acupuncture was associated with moderate improvement in pain relief immediately after treatment and up to 12 weeks later compared with sham acupuncture, but there was no improvement in function (125–130). Moderate-quality evidence showed that acupuncture was associated with moderately lower pain intensity and improved function compared with no acupuncture at the end of treatment (125). Low-quality evidence showed a small improvement in pain relief and function compared with

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medications (NSAIDs, muscle relaxants, or analgesics) (125).

Massage

Low-quality evidence showed no difference in pain between foot reflexology and usual care for patients with chronic low back pain (131–133). Moderate-quality evidence showed that massage improved short-term pain relief and function compared with other interventions (manipulation, exercise therapy, relaxation therapy, acupuncture, physiotherapy, or TENS) for patients with subacute to chronic low back pain, although effects were small (84, 86). Low-quality evidence showed that a combination of massage plus another intervention (exercise, exercise and education, or usual care) was superior to the other intervention alone for short-term pain in patients with subacute to chronic low back pain (84).

Spinal Manipulation

Low-quality evidence showed no difference in pain with spinal manipulation versus sham manipulation at 1 month (134, 135). Low-quality evidence showed that spinal manipulation slightly improved pain compared with an inert treatment (136–142). Moderate-quality evidence showed no clear differences in pain or function compared with another active intervention. Low-quality evidence showed that a combination of spinal manipulation with another active treatment resulted in greater pain relief and improved function at 1, 3, and 12 months compared with the other treatment alone (134, 143–147).

Ultrasound

Low-quality evidence showed no difference between ultrasound and sham ultrasound for pain at the end of treatment or 4 weeks after treatment (148–150). Low-quality evidence showed no difference between ultrasound and no ultrasound for pain or function (151, 152).

TENS

Low-quality evidence showed no difference between TENS and sham TENS for pain intensity or function at short-term follow-up (153). Low-quality evidence showed no difference between TENS and acupuncture in short- or long-term pain (154).

LLLT

Low-quality evidence showed that LLLT slightly improved pain compared with sham laser

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(155–157), and 1 RCT (155) showed that LLLT slightly improved function compared with sham laser.

Lumbar Support

Evidence was insufficient to compare lumbar support versus no lumbar support. Low-quality evidence showed no difference between a lumbar support plus exercise (muscle strengthening) versus exercise alone for pain or function at 8 weeks or 6 months (158). Low-quality evidence showed no clear differences between lumbar supports and other active treatments (traction, spinal manipulation, exercise, physiotherapy, or TENS) for pain or function (159–161).

Taping

Low-quality evidence showed no differences between Kinesio taping and sham taping for back-specific function after 5 or 12 weeks, although effects on pain were inconsistent between the 2 trials (162, 163). Low-quality evidence showed no differences between Kinesio taping and exercise for pain or function (164, 165).

Other Therapies

Evidence was insufficient to determine the effectiveness of electrical muscle stimulation, interferential therapy, short–wave diathermy, traction, or superficial heat or cold.

Radicular Low Back Pain

Exercise

Low-quality evidence showed that exercise resulted in small improvements in pain and function compared with usual care or no exercise (166-168).

Traction

Low-quality evidence showed no clear differences between traction and other active treatments, between traction plus physiotherapy versus physiotherapy alone, or between different types of traction in patients with low back pain with or without radiculopathy (169).

Other Therapies

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Evidence was insufficient for ultrasound, MCE, Pilates, tai chi, yoga, psychological therapies, multidisciplinary rehabilitation, acupuncture, massage, spinal manipulation, LLLT, eléctrical muscle stimulation, short-wave diathermy, TENS, interferential therapy, superficial heat or cold, lumbar support, and taping.

Harms of Nonpharmacologic Therapies

Evidence on adverse events from the included RCTs and systematic reviews was limited, and the quality of evidence for all available harms data is low. Harms were poorly reported (if they were reported at all) for most of the interventions.

Low-quality evidence showed no reported harms or serious adverse events associated with tai chi, psychological interventions, multidisciplinary rehabilitation, ultrasound, acupuncture, lumbar support, or traction (9, 95, 150, 170-174). Low-quality evidence showed that when harms were reported for exercise, they were often related to muscle soreness and increased pain, and no serious harms were reported. All reported harms associated with yoga were mild to moderate (119). Low-quality evidence showed that none of the RCTs reported any serious adverse events with massage, although 2 RCTs reported soreness during or after massage therapy (175, 176). Adverse events associated with spinal manipulation included muscle soreness or transient increases in pain (134). There were few adverse events reported and no clear differences between MCE and controls. Transcutaneous electrical nerve stimulation was associated with an increased risk for skin site reaction but not serious adverse events (177). Two RCTs (178, 179) showed an increased risk for skin flushing with heat compared with no heat or placebo, and no serious adverse events were reported. There were no data on cold therapy. Evidence was insufficient to determine harms of electrical muscle stimulation, LLLT, percutaneous electrical nerve stimulation, interferential therapy, short-wave diathermy, and taping.

Comparison of Conclusions With Those of the 2007 Guideline

Some evidence has changed since the 2007 ACP guideline and supporting evidence review.

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The 2007 review concluded that acetaminophen was effective for acute low back pain, based on indirect evidence from trials of acetaminophen for other conditions and trials of acetaminophen versus other analgesics. However, this update included a placebo-controlled RCT in patients with low back pain that showed no difference in effectiveness between acetaminophen and placebo (low-quality evidence). In addition, contrary to the 2007 review, current moderate-quality evidence showed that TCAs were not effective for chronic low back pain compared with placebo. Additional pharmacologic treatments addressed in the current review included duloxetine and the antiseizure medication pregabalin. Many conclusions about nonpharmacologic interventions are similar between the 2007 review and the update. Additional modalities assessed (with at least low-quality evidence) include mindfulness-based stress reduction, MCE, taping, and tai chi. Additional evidence or changes from the updated review include that superficial heat was found to be more effective for acute or subacute low back pain (moderate-quality evidence) and neither ultrasound nor TENS was shown to be effective compared with controls (low-quality evidence).

The Figure summarizes the recommendations and clinical considerations. Additional details on the evidence are available in Appendix Tables 1, 2, 3 and 4 and the accompanying evidence reviews (7, 8).

FIGURE.

Summary of the American College of Physicians guideline on noninvasive treatments for acute, subacute, or chronic low back pain.

COX-2 = cyclooxygenase-2; LLLT = low-level laser therapy; NSAID = nonsteroidal anti-inflammatory drug; SMR = skeletal muscle relaxant.



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Recommendations

Recommendation 1: Given that most patients with acute or subacute low back pain improve over time regardless of treatment, clinicians and patients should select nonpharmacologic treatment with superficial heat (moderate-quality evidence), massage, acupuncture, or spinal manipulation (low-quality evidence). If pharmacologic treatment is desired, clinicians and patients should select nonsteroidal anti-inflammatory drugs or skeletal muscle relaxants (moderate-quality evidence). (Grade: strong recommendation)

Clinicians should inform all patients of the generally favorable prognosis of acute low back pain with or without sciatica, including a high likelihood for substantial improvement in the first month (5, 180). Clinicians should also provide patients with evidence-based information with regard to their expected course, advise them to remain active as tolerated, and provide information about effective self-care options. Clinicians and patients should use a shared decision-making approach to select the most appropriate treatment based on patient preferences, availability, harms, and costs of the interventions. Nonpharmacologic interventions shown to be effective for improving pain and function in patients with acute or subacute low back pain include superficial heat (moderate-quality evidence and moderate improvement in pain and function) and massage (low-quality evidence and small to moderate improvement in pain and function). Low-quality evidence showed that acupuncture had a small effect on improving pain and spinal manipulation had a small effect on improving function compared with sham manipulation but not inert treatment. Harms of nonpharmacologic interventions were sparsely reported, and no serious adverse events were

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reported. Superficial heat was associated with increased risk for skin flushing, and massage and spinal manipulation were associated with muscle soreness.

We recommend that the choice between NSAIDs and SMRs be individualized on the basis of patient preferences and likely individual medication risk profile. Treatment with NSAIDs resulted in a small improvement in both pain intensity (moderate-quality evidence) and function (low-quality evidence), and treatment with SMRs resulted in a small improvement in pain relief (moderate-quality evidence). There was no evidence for the effect of SMRs on function. Nonsteroidal anti-inflammatory drugs are associated with gastrointestinal and renal risks. Clinicians should therefore assess renovascular and gastrointestinal risk factors before prescribing NSAIDs and recommend the lowest effective doses for the shortest periods necessary. Although they are associated with lower risk for adverse effects than nonselective NSAIDs, COX-2-selective NSAIDs were not assessed for improvement in pain or function. Skeletal muscle relaxants are associated with central nervous system adverse effects, especially sedation.

The updated evidence showed that acetaminophen was not effective at improving pain outcomes versus placebo. However, this study assessed pain at 3 weeks after the intervention, and evidence from head-to-head trials showed no difference between acetaminophen and NSAIDs. Low-quality evidence showed that systemic steroids were not effective in treating acute or subacute low back pain, and we recommend against these drugs for treatment of acute low back pain.

Recommendation 2: For patients with chronic low back pain, clinicians and patients should initially select nonpharmacologic treatment with exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction (moderate-quality evidence), tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, or spinal manipulation (low-quality evidence). (Grade: strong recommendation)

Nonpharmacologic interventions are considered as first-line options in patients with chronic low back pain because fewer harms are associated with these types of therapies than with

pharmacologic options. It is important that physical therapies be administered by providers with appropriate training. Moderate-quality evidence showed that exercise therapy resulted in small improvements in pain and function. Specific components associated with greater effects on pain included individually designed programs, supervised home exercise, and group exercise; regimens that included stretching and strength training were most effective. Moderate-quality evidence showed that, compared with usual care, multidisciplinary rehabilitation resulted in moderate pain improvement in the short term (<3 months), small pain improvement in the long term, and small improvement in function in both the short and long term. Low-quality evidence showed that multidisciplinary rehabilitation resulted in a moderate improvement in pain and a small improvement in function compared with no multidisciplinary rehabilitation. Acupuncture had a moderate effect on pain and function compared with no acupuncture (moderate-quality evidence) and a moderate effect on pain with no clear effect on function compared with sham acupuncture (low-quality evidence). Moderate-quality evidence showed that mindfulness-based stress reduction resulted in small improvements in pain and function (small effect), and 1 study showed that it was equivalent to CBT for improving back pain and function.

Low-quality evidence showed that tai chi had a moderate effect on pain and a small effect on function. Tai chi sessions in included studies lasted 40 to 45 minutes and were done 2 to 5 times per week for 10 to 24 weeks. Low-quality evidence showed that yoga improved pain and function by a moderate amount compared with usual care and by a small amount compared with education. Low-quality evidence showed that MCE had a moderate effect on pain and a small effect on function. Motor control exercise, tai chi, and yoga were favored over general exercise (low-quality evidence).

Low-quality evidence showed that progressive relaxation had a moderate effect on pain and function, electromyography biofeedback and CBT each had a moderate effect on pain and no effect on function, and operant therapy had a small effect on pain and no effect on function. Low-quality evidence showed that LLLT had a small effect on pain and function. Low-quality evidence showed that spinal manipulation had a small effect on pain compared with inert treatment but no effect compared with sham manipulation. There were no clear differences between spinal manipulation and other active interventions (moderate-quality evidence).

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Harms were poorly reported for nonpharmacologic therapies, although no serious harms were reported for any of the recommended interventions. Muscle soreness was reported for exercise, massage, and spinal manipulation.

Ultrasound, TENS, and Kinesio taping had no effect on pain or function compared with control treatments (low-quality evidence).

Recommendation 3: In patients with chronic low back pain who have had an inadequate response to nonpharmacologic therapy, clinicians and patients should consider pharmacologic treatment with nonsteroidal anti-inflammatory drugs as first-line therapy, or tramadol or duloxetine as second-line therapy. Clinicians should only consider opioids as an option in patients who have failed the aforementioned treatments and only if the potential benefits outweigh the risks for individual patients and after a discussion of known risks and realistic benefits with patients. (Grade: weak recommendation, moderate-quality evidence)

Pharmacologic therapy should be considered for patients with chronic low back pain who do not improve with nonpharmacologic interventions. Nonsteroidal anti-inflammatory drugs had a small to moderate effect on pain (moderate-quality evidence) and no to small effect on function (low-quality evidence) and should be the first option considered. Moderate-quality evidence showed no difference in pain improvement when different NSAIDs were compared with one another. Nonsteroidal anti-inflammatory drugs are associated with gastrointestinal and renal risks. Clinicians should therefore assess renovascular and gastrointestinal risk factors before prescribing NSAIDs and should recommend the lowest effective doses for the shortest periods necessary. COX-2-selective NSAIDs were not assessed for improvement in pain or function, although they are associated with lower risk for adverse effects than nonselective NSAIDs.

For second-line therapies, moderate-quality evidence showed that tramadol had a moderate effect on pain and a small effect on function in the short term. Of note, tramadol is a narcotic and, like other opioids, is associated with the risk for abuse (181). Moderate-quality evidence showed that duloxetine had a small effect on pain and function.

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Moderate-quality evidence showed that opioids (morphine, oxymorphone, hydromorphone, and tapentadol) had a small effect on short-term pain and function. Low-quality evidence showed that buprenorphine (patch or sublingual) resulted in a small improvement in pain. Opioids should be the last treatment option considered and should be considered only in patients for whom other therapies have failed because they are associated with substantial harms. Moderate-quality evidence showed no difference in pain or function when different long-acting opioids were compared with one another. Harms of short-term use of opioids include increased nausea, dizziness, constipation, vomiting, somnolence, and dry mouth compared with placebo. Studies assessing opioids for the treatment of chronic low back pain did not address the risk for addiction, abuse, or overdose, although observational studies have shown a dose-dependent relationship between opioid use for chronic pain and serious harms (182).

Moderate-quality evidence showed that TCAs did not effectively improve pain or function (low-quality evidence) in patients with chronic low back pain, which is contrary to the 2007 guideline. In addition, moderate-quality evidence showed that SSRIs did not improve pain.

Areas of Inconclusive Evidence

Evidence is insufficient or lacking to determine treatments for radicular low back pain. Most RCTs enrolled a mixture of patients with acute, subacute, and chronic low back pain, so it is difficult to extrapolate the benefits of treatment compared with its duration. Use of opioids for chronic pain is an important area that requires further research to compare benefits and harms of therapy. The evidence is also insufficient for most physical modalities. Evidence is insufficient on which patients are likely to benefit from which specific therapy. Evidence on patient-important outcomes, such as disability or return to work, was largely unavailable, and available evidence showed no clear connection with improvements in pain.

High-Value Care

Clinicians should reassure patients that acute or subacute low back pain usually improves

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over time, regardless of treatment. Thus, clinicians should avoid prescribing costly and potentially harmful treatments for these patients, especially narcotics. In addition, systemic steroids were not shown to provide benefit and should not be prescribed for patients with acute or subacute low back pain, even with radicular symptoms. For treatment of chronic low back pain, clinicians should select therapies that have the fewest harms and lowest costs because there were no clear comparative advantages for most treatments compared with one another. Clinicians should avoid prescribing costly therapies; those with substantial potential harms, such as long-term opioids (which can be associated with addiction and accidental overdose); and pharmacologic therapies that were not shown to be effective, such as TCAs and SSRIs.

Appendix: Detailed Methods

The evidence review was conducted by the AHRQ's Pacific Northwest Evidence-based Practice Center. Details of the ACP guideline development process can be found in ACP's methods paper (12). Disclosures of interests and management of any conflicts can be found at www.acponline.org/clinical_information/guidelines/guidelines/conflicts_cgc.htm.

Key Questions Addressed

- 1. What are the comparative benefits and harms of different pharmacologic therapies for acute or chronic nonradicular low back pain, radicular low back pain, or spinal stenosis, including NSAIDs, acetaminophen, opioids, muscle relaxants, antiseizure medications, antidepressants, corticosteroids, and topical or patch-delivered medications?
- 2. What are the comparative benefits and harms of different nonpharmacologic, noninvasive therapies for acute or chronic nonradicular low back pain, radicular low back pain, or spinal stenosis, including but not limited to interdisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, TENS, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low-level lasers?

Search Strategy

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Reviewers searched MEDLINE, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews for trials published from January 2008 through April 2015. Searches were updated through November 2016. Studies published before 2008 were identified using the 2007 ACP/APS systematic reviews (10, 11).

Quality Assessment

Randomized trials were evaluated using methods developed by the Cochrane Back Review Group and the AHRQ (183), and systematic reviews were assessed using AMSTAR (A Measurement Tool to Assess Systematic Reviews) (184).

Population Studied

Adults with acute, subacute, or chronic nonradicular low back pain, radicular low back pain, or symptomatic spinal stenosis.

Interventions Evaluated

Oral or topical pharmacologic therapies included NSAIDs, acetaminophen, opioids, tramadol and tapentadol, antidepressants, SMRs, benzodiazepines, corticosteroids, antiepileptic medications, capsaicin, and lidocaine.

Noninvasive, nonpharmacologic therapies included interdisciplinary or multicomponent rehabilitation (physical therapy plus psychological therapy with some coordination), psychological therapies, exercise and related interventions (such as yoga or tai chi), complementary and alternative medicine therapies (spinal manipulation, acupuncture, and massage), passive physical modalities (such as heat, cold, ultrasound, TENS, electrical muscle stimulation, interferential therapy, short-wave diathermy, traction, LLLT, and lumbar supports/braces), and taping.

Comparators

Interventions were compared with each other or with placebo (drug trials), sham (functionally inert) treatments, or no treatment.

Outcomes

Outcomes included reduction or elimination of low back pain (including related leg

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symptoms), improvement in back-specific and overall function, improvement in health-related quality of life, reduction in work disability and return to work, global improvement, number of back pain episodes or time between episodes, patient satisfaction, and adverse effects of interventions.

Timing

Timing of outcomes was stratified as long-term (≥1 year) and short-term (\leq 6 months).

Setting

Settings included inpatient and outpatient.

Target Audience

The target audience includes all clinicians.

Target Patient Population

The target patient population includes adults with acute (<4 weeks), subacute (4 to 12 weeks), or chronic (>12 weeks) nonradicular low back pain, radicular low back pain, or symptomatic spinal stenosis. Children or adolescents with low back pain; pregnant women; and patients with low back pain from sources outside the back (nonspinal low back pain), fibromyalgia or other myofascial pain syndromes, and thoracic or cervical back pain are not included.

Peer Review

The AHRQ systematic review was sent to invited peer reviewers and posted on the AHRQ Web site for public comments. The accompanying evidence reviews (7, 8) also underwent a peer review process through the journal. The guideline underwent a peer review process through the journal and was posted online for comments from ACP Regents and ACP Governors, who represent ACP members at the regional level.

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Burton "Bud" Rose, MD, founder, shares the inspiration behind the creation of UpToDate



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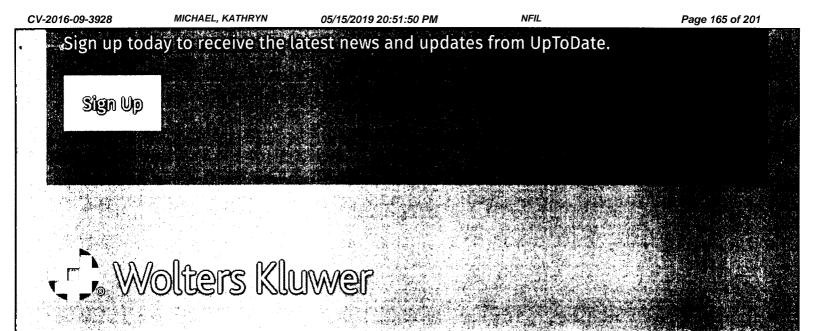
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Updating

UpToDate is updated daily following a continual comprehensive review of peer-reviewed journals, clinical databases and other resources (see the Evidence section for a detailed list). Topics in UpToDate are revised whenever important new information is published, not according to any specific time schedule. Updates are integrated carefully, with specific statements as to how the new findings should be applied clinically, and after extensive peer review.

Important and practice-changing updates, in addition to appearing in a traditional UpToDate topic, are highlighted in our What's New section and in a topic called "Practice Changing UpDates." Practice Changing UpDates focus on changes that may have significant and broad impact on practice, and therefore do not represent all updates that affect practice.

Peer Review

The deputy editor for a specialty, as well as the editor-in-chief and/or section editors assigned to a topic, review all UpToDate content, including new topics, updates and recommendations. In addition, each UpToDate specialty has assembled a group of peer reviewers, often in conjunction with a sponsoring specialty society, who are responsible for reviewing selected topics in each specialty. Finally, any comments from users of UpToDate are formally addressed, with changes and/or additions incorporated as necessary.

Policy Review

UpToDate's policies and procedures are continuously reviewed in consultation with our Evidence-Based Medicine Advisory Group led by Dr. Gordon Guyatt from McMaster University.

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Authors

All topics in UpToDate are written by the listed authors in conjunction with a deputy editor. Authors are identified as experts by the editors-in-chief, our editorial staff and the participating societies. All material is originally prepared by the contributing author(s) whose name(s) and affiliation(s) appear in the upper left corner of each topic. This material is reviewed extensively by our physician editors and peer reviewers for accuracy and completeness of the literature search, and for consistency with all aspects of the editorial policy. Physician editors suggest changes to ensure that topics summarize the relevant evidence and that recommendations are consistent with the evidence, with our understanding of patients' values and preferences, and with our editorial policy. Some of the content may be taken from other topics in UpToDate. In such cases, the text is hyperlinked to the topic from which it originated.

Occasionally authors of a particular topic are replaced. A new author is required to thoroughly review the topic and make necessary revisions, but is not required to completely rewrite the topic. The revised topic undergoes the same peer review process as new topics in UpToDate. When an author is replaced, the previous author is acknowledged at the bottom of the topic for at least one year.

UpToDate Pathways and Lab Interpretation topics

UpToDate Pathways and Lab Interpretation topics (require a subscription to UpToDate Advanced) are prepared by the listed Authors in conjunction with UpToDate Deputy Editors, based exclusively on content synthesized from UpToDate topics that have been developed in accord with the above policies. The UpToDate Pathways and Lab Interpretation topics are electronically linked to the underlying UpToDate topics within our editorial system, so that a revision or update to a relevant section in an UpToDate topic will generate a simultaneous review and revision of the related UpToDate Pathway and/or Lab Interpretation topic(s). The UpToDate Pathways and Lab Interpretation topics themselves therefore directly reflect the updating policies for the underlying topics, and the underlying evidence is explicitly available in the linked topics. Any comments from users of UpToDate are formally addressed, with changes and/or additions incorporated as necessary.

Evidence

UpToDate follows a hierarchy of evidence consistent with most evidence-based resources. At the

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top of the hierarchy are meta-analyses of randomized trials of high methodological quality, followed by randomized trials with methodological limitations, observational studies and unsystematic clinical observations. Inferences are stronger when the evidence is summarized in systematic reviews of the literature that present all relevant data.

Each topic has an author who is an expert in the area discussed, and at least two separate physician reviewers. This group works together to perform a comprehensive review of the literature and carefully select studies for presentation based on the quality of the study, the hierarchy of evidence discussed above, and clinical relevance. When current, high-quality systematic reviews are available, UpToDate topics and recommendations rely heavily on these reviews. When such reviews are unavailable, UpToDate summarizes the key studies bearing on the clinical issues at hand. Systematic reviews and the design of primary studies (eg, randomized trials, observational studies) are often identified explicitly in the text, with the relevant data provided. However, in cases where either the type of study or the data are not stated explicitly, users can click on the reference and bring up the Medline abstract to obtain this information. Evidence is derived from a number of resources, including but not limited to:

- Hand-searching of over <u>430 peer-reviewed journals</u>
- Electronic searching of databases including Medline, Cochrane Library, and BMJ Best Practice
- Guidelines that adhere to principles of evidence evaluation described above
- Published information regarding clinical trials such as reports from the US Food and Drug
 Administration and the European Medicines Agency, as well as other sources of
 information produced by governmental and nongovernmental agencies such as the
 Centers for Disease Control and Prevention and the World Health Organization
- Proceedings of major national and international scientific meetings
- The clinical experience and observations of our authors, editors and peer reviewers

Recommendations

Structured Questions

UpToDate's process of arriving at recommendations involves constructing a structured clinical question. That structure includes carefully defining the patient population of interest, the alternative management strategies, and the outcomes of importance to patients (PICO format: Population, Intervention, Comparators, Outcomes).

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Values and Preferences

A fundamental principle of evidence-based medicine, as described by Dr. Gordon Guyatt from McMaster University, is that "Evidence alone is never sufficient to make a clinical decision. Decision makers must always trade the benefits and risks, inconvenience, and costs associated with alternative management strategies, and in doing so consider the patient's values". Expertise is thus required to move from evidence to recommendations.

This principle has led some evidence-based resources to avoid making specific recommendations for patient care, since the recommendation needs to account for all of the factors cited. UpToDate has taken a different approach. It is the policy of UpToDate to make specific recommendations for patient care whenever possible.

Recommendations in UpToDate are based on a synthesis of evidence, including that obtained from clinical trials as well as clinical experience; whenever possible, the evidentiary basis for recommendations is stated explicitly. When there is no published systematic evidence available (eg, prednisone dosing regimen in pulmonary sarcoidosis), recommendations are based on the unsystematic clinical observations of our experts and reviewers, and on pathophysiologic rationale.

UpToDate recommendations identify situations in which different decisions might be appropriate for patients with different values and preferences. Furthermore, UpToDate recognizes that recommendations will not apply to every patient, and counts on clinicians to evaluate the recommendations in light of the individual circumstances of their patient. Nevertheless, UpToDate feels that providing recommendations based on a sophisticated understanding of the clinical issues, the best evidence, and a consideration of patient values and preferences allows clinicians to make informed decisions with and for their patients.

As discussed in the following section, UpToDate commonly uses the terminology "We recommend..." or "We suggest..." when describing recommended courses of action, since recommendations generally reflect a consensus of the author(s) and editors of a topic. When there are disagreements, this same wording is used; however, the recommendations are those of the author(s), and the disagreement among experts is discussed within the text. If other topics in UpToDate make alternative recommendations, those topics and recommendations are hyperlinked.

Grading Process

UpToDate began grading recommendations for treatment and screening in 2006. This is a continuing process, with thousands of graded recommendations in the program, although not all recommendations have yet been graded. Graded recommendations appear in the Summary

and Recommendations sections at the end of topics.

UpToDate uses the GRADE system.² Grades have two components, a number (1 or 2) reflecting the strength of the recommendation and a letter (A, B, or C) reflecting the quality of the evidence supporting that recommendation.

A Grade 1 recommendation is a strong recommendation to do (or not do) something, where the benefits clearly outweigh the risks (or vice versa) for most if not all patients. A Grade 2 recommendation is a weaker recommendation, where the risks and benefits are more closely balanced or are more uncertain. The majority of recommendations will be grade 2 recommendations. UpToDate uses a wording that reflects the strength of the recommendation: Strong (Grade 1) recommendations are "recommended" and weak (Grade 2) recommendations are "suggested."

Grade A evidence refers to high-quality evidence that comes from consistent results from well-performed randomized controlled trials, or overwhelming evidence of some other sort (such as well-executed observational studies with very strong effects). Grade B evidence refers to moderate-quality evidence from randomized trials that suffer from serious flaws in conduct, inconsistency, indirectness, imprecise estimates, reporting bias, or some combination of these limitations, or from other study designs with special strength. Grade C evidence refers to low-quality evidence from observational evidence, or from controlled trials with several very serious limitations.

Additional detailed information about the <u>GRADE system</u>, including an online grading tutorial, is available for those interested in learning more about how we apply evidence grades and for those who wish to use the system.

Grading recommendations involves subjective judgments about evidence, benefits and harms. Users of UpToDate are welcome to communicate concerns about grades to the editorial staff.

Moving from Evidence to Recommendations

The following table presents the criteria that UpToDate authors and editors consider when weighing the advantages and disadvantages of treatments, both in order to decide on a recommendation and to grade the strength of that recommendation.

Issue (and what should be considered)

Recommended process

Quality of evidence

Strong recommendations usually require at

CV-2016-09-3928	8 MICHAEL, KATHRYN	05/15/2019 20:51:50 PM	least moderate-quality evidence for all the critical outcomes. The lower the quality of evidence, the less likely there should be a strong recommendation.		
	Relative importance of the outcomes (benefits, harms, burdens)		Authors and editors consider the relative values and preferences that patients and oth stakeholders place on outcomes and the variability in values and preferences across patients. If values and preferences vary wide a strong recommendation becomes less likel		
	Baseline risks of adverse outcomes (typically most relevant for benefits)		The higher the baseline risk of an adverse outcome, the greater the magnitude of benefa treatment will offer, and the more likely the should be a strong recommendation. If the baseline risk is very different for two subpopulations, then UpToDate may make separate recommendations for these different groups.		
	Magnitude of effect (benefi reduction in RR; harms - eg burden)	- 1	Larger relative risk reductions with treatment make a strong recommendation for treatment more likely, while larger increases in the relative risk of harms make a strong recommendation for treatment less likely.		
	Absolute magnitude of the effect (benefits, harms, burden)		The larger the absolute benefits with treatment, the greater the likelihood of a strong recommendation in favor of treatmen. The larger the absolute increase in harms, th less likely there should be a strong recommendation in favor of treatment.		
	Precision of the estimates (benefits, harms and burde		The greater the precision, the more likely the should be a strong recommendation.		
	Cost	·	The higher the incremental cost, the less the likelihood of a strong recommendation in favor of a treatment.		

- for Evidence-based Clinical Practice, 2nd ed, McGraw-Hill, New York 2008.
- 2. Guyatt GH, Oxman AD, Vist GE, et al, for the GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008; 336:924.

This policy last reviewed on January 22, 2018.

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Treatment of acute low back pain

Authors: Christopher L Knight, MD, Richard A Deyo, MD, MPH, Thomas O Staiger, MD, Joyce E Wipf, MD

Section Editor: Steven J Atlas, MD, MPH

Deputy Editor: Lisa Kunins, MD

All topics are updated as new evidence becomes available and our peer review process is complete.

Literature review current through: Mar 2019. | This topic last updated: Dec 06, 2017.

PLAINTIFF'S EXHIBIT

INTRODUCTION

It is estimated that up to 84 percent of adults have low back pain at some time in their lives [1,2]. The vast majority of patients seen in primary care (>85 percent) will have nonspecific low back pain, meaning that the patient has back pain in the absence of a specific underlying condition that can be reliably identified [3-5]. For most of these individuals, episodes of back pain are self-limited. Patients who continue to have back pain beyond the acute period (four weeks) have subacute back pain (lasting between 4 and 12 weeks), and some may go on to develop chronic back pain (lasting >12 weeks) [6].

This discussion focuses on the initial treatment of nonspecific acute back pain. The treatment of acute low back pain from specific conditions is discussed in the appropriate topics. As examples:

- Treatment for vertebral compression fracture (see "Osteoporotic thoracolumbar vertebral compression fractures: Clinical manifestations and treatment")
- Treatment for lumbosacral radiculopathy (see <u>"Acute lumbosacral radiculopathy: Treatment</u> and prognosis")
- Treatment for lumbar spinal stenosis (see "Lumbar spinal stenosis: Treatment and prognosis")

The evaluation of low back pain, occupational back pain, and management of patients with

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occupational, subacute (4 to 12 weeks), and chronic (>12 weeks) back pain are also discussed separately. (See "Evaluation of low back pain in adults" and "Occupational low back pain:

Evaluation and management" and "Subacute and chronic low back pain: Nonpharmacologic and pharmacologic treatment" and "Subacute and chronic low back pain: Nonsurgical interventional treatment" and "Subacute and chronic low back pain: Surgical treatment".)

GENERAL APPROACH TO CARE

The goal of care for patients with acute low back pain is short-term symptomatic relief, since most will improve within four weeks. (See <u>'Prognosis'</u> below and <u>"Evaluation of low back pain in adults"</u>, section on 'Risk assessment subacute back pain'.)

We typically advise nonpharmacologic treatment with superficial heat. Massage, acupuncture, and spinal manipulation are other reasonable options depending upon patient preference and their cost and accessibility. There are no data demonstrating superiority of one modality over another [7]. For patients who prefer pharmacotherapy or in whom nonpharmacologic approaches are inadequate, we suggest a nonsteroidal antiinflammatory drug (NSAID) with or without a skeletal muscle relaxant rather than <u>acetaminophen</u> for pharmacologic therapy. (See <u>'Nonpharmacologic therapies'</u> below and <u>'Pharmacotherapy'</u> below.)

This approach is consistent with the 2017 updated guideline of the treatment of acute, subacute, and chronic low back pain from the American College of Physicians [4].

We do not advise bed rest for patients with acute low back pain. Patients who are treated with bed rest have more pain and slower recovery than ambulatory patients [8]. Activity modification should generally be minimal, with patients returning to activities of daily living and work as soon as possible. If activity is painful or increases pain, we advise patients to do as much as they can and gradually increase activity as tolerated. We emphasize the importance of avoiding prolonged periods of inactivity. However, we do not routinely refer patients with acute low back pain for exercise or physical therapy, and instead reserve those services for patients not improving with initial treatment or with risk factors for developing chronic low back pain (eg, poor functional or health status, psychiatric comorbidities). (See 'Exercise and physical therapy' below.)

Return-to-work recommendations should be individualized. For example, an office worker who has

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control over the pace of work, positioning while working, and/or work hours may be able to return to work promptly. However, those with physically demanding jobs may not be able to return to work immediately if light-duty options are not available.

Return-to-work advice for patients with occupational low back pain is discussed elsewhere. (See "Occupational low back pain: Evaluation and management", section on 'Return-to-work issues'.)

NONPHARMACOLOGIC THERAPIES

Evidence of the effectiveness of nonpharmacologic therapies is generally of low to moderate quality [7]. The choice among these options depends upon patient preference and their cost and accessibility.

Heat — Heat is often applied with the rationale that it may reduce muscle spasm. A 2006 systematic review including six studies of low back pain found moderate evidence that a heat wrap may reduce pain and disability for patients with pain of less than three months' duration, although the benefit was small and short-lived [9].

Massage — There is no evidence that massage offers clinical benefits for acute low back pain [10]. However, a randomized trial found that compared with usual care, when massage was chosen by the patient, it was associated with increased patient satisfaction [11].

Acupuncture — Acupuncture may be a reasonable option for interested patients with access to an acupuncturist. The evidence of benefit in acute low back pain is limited. Randomized trials of acupuncture tend to be small and heterogeneous in methodology, and blinding is difficult. Systematic reviews of acupuncture for acute low back pain have found inconsistent results [12]. Acupuncture is safe with few side effects. (See "Acupuncture", section on 'Adverse events'.)

There is more evidence to support the use of acupuncture in chronic low back pain. (See "Acupuncture", section on 'Low back pain'.)

Spinal manipulation — Spinal manipulation is a form of manual therapy that involves the movement of a joint near the end of the clinical range of motion.

Based upon the available evidence, spinal manipulation appears to confer modest improvements

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in pain and function. A 2017 systematic review and meta-analysis of spinal manipulative therapy for acute low back pain examined 26 randomized controlled trials [13]. Fifteen trials (1711 patients) provided moderate-quality evidence of improvement in visual analog pain scale, and 12 trials (1381 patients) showed moderate-quality evidence of improvement in function. Comparator groups were heterogeneous and included analgesics, exercise, and physical therapy. Minor transient adverse events such as increased pain, muscle stiffness, and headache were reported in 50 to 67 percent of patients. Serious adverse events (eg, worsening lumbar disc herniation, cauda equina syndrome) following spinal manipulation are rare.

Integrating spinal manipulation into the therapeutic plan for individual patients should depend upon their preferences and access to this type of intervention. There is little evidence to guide the duration of therapy. Most clinical trials have evaluated courses of twice-weekly manipulation for two to three weeks. There are no data on selecting practitioner type (eg, chiropractor, osteopath, massage therapist, physical therapist). (See "Spinal manipulation in the treatment of musculoskeletal pain", section on 'Risks of spinal manipulation'.)

Exercise and physical therapy — Exercise therapy includes both self-care exercises done by the patient and supervised exercises in the context of physical therapy. In general, we do not refer patients with acute low back pain for exercise or physical therapy. However, we selectively refer patients with risk factors for developing chronic low back pain (eg, poor functional or health status, psychiatric comorbidities) who may benefit from immediate education by a physical therapist on how to avoid recurrences, appropriate levels of activity, and exercises to begin after the acute phase [14]. (See 'Prognosis' below and "Exercise-based therapy for low back pain".)

Although some studies do show modest efficacy of exercise therapy in selected cases of acute low back pain (<4 weeks) [15,16], systematic reviews have not clearly demonstrated a treatment benefit of generalized exercise therapy compared with other conservative treatments [17-20]. As an example, in one systematic review of 11 randomized trials of exercise in patients with acute low back pain, exercise therapy was not more effective than no treatment or other conservative treatments [18], which included nonsteroidal antiinflammatory drugs (NSAIDs)/other analgesics, patient education programs, and/or advice to stay active. A subsequent randomized trial in patients with back pain for 16 days or less compared four sessions of physical therapy with usual care over four weeks; the intervention led to a small improvement in a disability index score at four weeks that was not considered to be clinically significant, and no difference at one year [21].

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Treatment of acute low back pain - UpToDate

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Early referral to a physical therapist may benefit patients with acute back pain who are at higher risk of developing chronic back pain, but this is unproven and may relate to education provided rather than exercise and therapy performed. While studies that have assessed such an approach showed improved outcomes for disability and lost work time, the majority of patients in these studies (>80 percent) had subacute or chronic rather than acute low back pain [14,22,23].

There is evidence to support exercise therapy for patients with subacute and chronic low back pain [15-17,24]. (See 'Prognosis' below and "Exercise-based therapy for low back pain", section on 'Rationale for exercise'.)

Other — Many other interventions have been suggested for acute low back pain with little or no evidence to support their use [10,11].

- **Cold** Application of cold is often recommended for patients with acute back pain, with the rationale that it may help reduce edema. However, cold applied superficially does not penetrate far below the skin. A 2006 systematic review found only three studies evaluating cold for low back pain and was unable to find evidence of benefit [9].
- Muscle energy technique The muscle energy technique is a treatment that involves
 alternating periods of resisted muscle contractions and assisted stretching. A 2015 systematic
 review of randomized trials found no evidence of effectiveness in patients with acute low back
 pain [19].
- **Traction** There is no evidence that traction is beneficial for acute low back pain. A 2013 systematic review including 32 randomized trials of traction for low back pain (with or without sciatica) concluded that traction provides no benefits [25].
- Lumbar supports There is no evidence to suggest that lumbar supports such as corsets or braces have therapeutic value for most patients with acute low back pain [26].
- Mattress recommendations The role of mattresses has not been studied in acute low back pain.
- Yoga Studies on yoga and back pain have primarily focused on chronic low back pain.
 There is no evidence to support the use of yoga in acute low back pain. (See <u>"Exercise-based therapy for low back pain"</u>, section on 'Yoga'.)

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Paraspinal injections — A variety of injections (eg, epidural spinal, trigger point, or facet join injections) have been advocated for patients with back pain. There is little evidence to support any type of injection for nonspecific acute low back pain. Injections for lumbosacral radiculopathy, spinal stenosis, and subacute and chronic low back pain are discussed elsewhere. (See "Subacute and chronic low back pain: Nonsurgical interventional treatment", section on 'Glucocorticoid and other injections' and "Acute lumbosacral radiculopathy: Treatment and prognosis", section on 'Epidural glucocorticoids' and "Lumbar spinal stenosis: Treatment and prognosis", section on 'Epidural injections'.)

PHARMACOTHERAPY

Initial therapy — If pharmacotherapy is used, we suggest a trial of short-term (two to four weeks) treatment of a nonsteroidal antiinflammatory drug (NSAID).

Nonsteroidal antiinflammatory drugs — We start with NSAID therapy in patients with acute low back pain without contraindications to this therapy. Many NSAID options exist (<u>table 1</u>). We generally start with either <u>ibuprofen</u> (400 to 600 mg four times daily) or <u>naproxen</u> (250 to 500 mg twice daily). Doses should be decreased as tolerated.

NSAIDs provide modest symptomatic relief for acute low back pain [27-29]. In a 2008 systematic review and meta-analysis of 11 randomized trials, global symptomatic improvement after one week was modestly greater for patients with acute low back pain treated with NSAIDs compared with placebo (risk ratio [RR] 1.19; 95% CI 1.07-1.35) [28]. NSAIDs were associated with more side effects compared with either placebo or acetaminophen.

NSAIDs may have significant renal, gastrointestinal, and cardiovascular adverse effects and may be contraindicated in some patients. All NSAID toxicities are more common in older patients. The adverse effects of nonselective NSAIDs and cyclooxygenase (COX)-2 inhibitors are discussed elsewhere. (See "Nonselective NSAIDs: Overview of adverse effects" and "NSAIDs: Adverse cardiovascular effects" and "Overview of selective COX-2 inhibitors", section on 'Toxicities and possible toxicities'.)

Limited benefit of acetaminophen — <u>Acetaminophen</u> has historically been considered an option for first-line therapy for low back pain. However, evidence of efficacy has been mixed in the

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past [28,30], and a 2016 Cochrane review [31] concluded that there was high-quality evidence that acetaminophen showed no benefit compared with placebo in acute low back pain. Given that acetaminophen has clear risks and questionable benefit, we do not recommend it as initial therapy for the majority of patients with acute low back pain. In selected patients for whom there are no safe alternatives and acetaminophen is the least potentially harmful treatment, we believe it reasonable to consider a trial of acetaminophen as initial therapy.

Hepatotoxicity is the primary concern with <u>acetaminophen</u> use. The risk of liver injury is doserelated, but the dose causing toxicity may vary from patient to patient. Factors that can predispose patients to hepatotoxicity include chronic alcohol ingestion, medications that affect the cytochrome P2E1 (CYP2E1) enzyme system of the liver, malnutrition, and older age. In patients with risk factors for hepatotoxicity, we recommend limiting acetaminophen to ≤2 g per day. Many combination analgesics, both prescription and over-the-counter, contain acetaminophen, and the total dose of acetaminophen should be taken into account when patients are taking multiple medications. (See <u>"Acetaminophen (paracetamol) poisoning in adults: Pathophysiology, presentation, and diagnosis", section on 'Clinical factors influencing toxicity'.)</u>

Other possible adverse effects that have been associated with <u>acetaminophen</u> include chronic kidney disease, hypertension, and peptic ulcer disease. (See <u>"Epidemiology and pathogenesis of analgesic-related chronic kidney disease"</u>, section on 'Acetaminophen' and <u>"NSAIDs and acetaminophen</u>: Effects on blood pressure and hypertension", section on 'Effects of <u>acetaminophen</u> on blood pressure' and <u>"Unusual causes of peptic ulcer disease"</u>, section on 'Acetaminophen'.)

Second-line therapy — For patients with pain refractory to initial pharmacotherapy, we suggest the addition of a nonbenzodiazepine muscle relaxant. In patients who cannot tolerate or have contraindications to muscle relaxants, combining NSAIDs and <u>acetaminophen</u> is another option, though there are few data to support the use of this combination.

Combination with muscle relaxants — Muscle relaxants are a diverse group of drugs with similar physiologic effects including analgesia and a degree of skeletal muscle relaxation or relief of muscle spasm. They include benzodiazepines, <u>cyclobenzaprine</u>, <u>methocarbamol</u>, <u>carisoprodol</u>, <u>baclofen</u>, <u>chlorzoxazone</u>, <u>metaxalone</u>, <u>orphenadrine</u>, and <u>tizanidine</u>.

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Patients who can tolerate the potential sedating effects of these medications may benefit from the addition of a nonbenzodiazepine muscle relaxant to initial pharmacotherapy with NSAIDs or acetaminophen. We generally do not start these medications as initial therapy, as they tend to have sedating side effects that limit patients' ability to work or drive. Risks of these agents increase with age, and these agents should be used with caution in older adults.

<u>Cyclobenzaprine</u> is a reasonable first-choice drug. For patients who cannot tolerate the sedating effects of muscle relaxants during the daytime, NSAIDs or <u>acetaminophen</u> during the day with muscle relaxants before bedtime may be helpful. Benzodiazepines should not be used because they are not effective in improving pain or functional outcome [32], and there is potential for abuse.

• Efficacy – Muscle relaxants provide symptomatic relief for patients with acute low back pain. A 2003 systematic review found high-quality evidence that nonbenzodiazepine muscle relaxants are more effective than placebo for short-term relief of acute low back pain (RR 0.80, 95% CI 0.71-0.89) [33]. Available comparative data suggests little difference between nonbenzodiazepine agents [33]. There is some evidence that cyclobenzaprine, methocarbamol, carisoprodol, and tizanidine are more effective than other muscle relaxants [34,35].

Evidence on combination therapy with NSAIDs is mixed. A randomized trial in 197 patients with acute low back pain comparing treatment for one week with aceclofenac 100 mg twice daily with or without the addition of <u>tizanidine</u> 2 mg twice daily found improved pain relief and decreased functional impairment with combination therapy [36]. However, other randomized trials have found no additional benefits to adding either <u>cyclobenzaprine</u> to <u>naproxen</u> therapy or <u>ibuprofen</u> to cyclobenzaprine therapy [37,38].

There are no studies evaluating the combination of <u>acetaminophen</u> with muscle relaxants.

Adverse effects – The primary adverse effects (sedation, dizziness) of muscle relaxants
relate to their central nervous system and anticholinergic activity; these are more likely to be
problematic in older patients. Dependence and abuse potential are concerns with
benzodiazepines. <u>Carisoprodol</u> also has abuse potential, particularly in patients with a history
of substance abuse [39]. (See "<u>Drug prescribing for older adults"</u>.)

Refractory or severe pain — Evidence to support the use of opioids and tramadol in acute low

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back pain is limited. These agents should be reserved for patients who do not have adequate relief from or have contraindications to other agents.

Opioids — Opioids have few benefits when added to NSAID therapy. If opioids are used for acute low back pain, the duration of therapy should be brief. We agree with a 2016 US Centers for Disease Control and Prevention (CDC) recommendation limiting duration of opioid therapy for acute pain to less than three days for most patients unless circumstances clearly warrant additional therapy. Even in those cases, more than seven days is rarely needed [40].

There are few data on the efficacy and safety of opioids for acute low back pain [41]. Most studies of opioids focus on chronic back pain and are not generalizable to acute back pain. One randomized trial in patients presenting to the emergency department with ≤2 weeks of acute, nontraumatic, nonradicular low back pain found no difference in pain or disability after seven days of <u>naproxen</u> alone compared with naproxen plus <u>oxycodone/acetaminophen</u> [38].

The appropriate opioid dosing regimen is unknown. One trial comparing scheduled dosing of opioids with as-needed dosing found better outcomes in the scheduled dosing group [42]. One strategy is to limit opioids to bedtime use to facilitate sleep and reduce the chances of developing dependence or tolerance.

Adverse effects of opioids include sedation, confusion, nausea, and constipation. Respiratory depression is an issue at higher doses but rarely at the doses used for acute low back pain. As with all medications, older patients are more susceptible to side effects. Patients given combination drugs containing <u>acetaminophen</u> or NSAIDs should be advised not to use them concurrently with over-the-counter analgesics without carefully reviewing the contents with a health care professional.

Misuse is a concern with opioids. Addiction and abuse are rare with short-term prescription for acute pain [43] but more common in patients using opioids for the treatment of chronic back pain [44,45].

Tramadol — <u>Tramadol</u> is an opioid agonist that also blocks reuptake of serotonin and norepinephrine [46]. We prescribe tramadol similarly to opioids, limiting regular use to a few days and total use to two weeks. Tramadol may have a lower risk of constipation and dependence than conventional opioids but carries the risk of serotonin syndrome, especially when combined with

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other serotonergic agents [46,47]. (See "Cancer pain management with opioids: Optimizing analgesia", section on 'Mixed mechanism drugs: Tramadol and tapentadol' and "Use of opioids in the management of chronic non-cancer pain", section on 'Opioids'.)

While randomized trials have shown that <u>tramadol</u> may be effective for chronic back pain, there are few data evaluating tramadol for acute low back pain [48-50].

Other medications — Drugs with limited or no evidence of effectiveness include:

Antidepressants – There is no evidence to support the use of antidepressants in treatment of
acute low back pain. However, in patients with concurrent depression, we ensure that the
depression is appropriately treated. (See "Unipolar major depression in adults: Choosing initial
treatment".)

These medications may be considered in the management of subacute or chronic back pain. (See "Subacute and chronic low back pain: Nonpharmacologic and pharmacologic treatment", section on 'Antidepressants'.)

• **Systemic glucocorticoids** – There is no evidence to support the use of systemic glucocorticoids in acute nonspecific back pain [7]. Small randomized trials in patients with nontraumatic back pain presenting to the emergency department comparing systemic steroids with placebo have found no benefits [51,52].

The use of systemic glucocorticoids for the treatment of acute lumbosacral radiculopathy is discussed elsewhere. (See <u>"Acute lumbosacral radiculopathy: Treatment and prognosis"</u>, <u>section on 'Systemic glucocorticoids'</u>.)

- Antiepileptics There is no evidence to support the use of antiepileptics in treatment of
 acute low back pain. These medications may be considered in the management of subacute
 or chronic back pain. (See "Subacute and chronic low back pain: Nonpharmacologic and
 pharmacologic treatment", section on 'Antiepileptic medications'.)
- **Topical agents** There is low-quality evidence that topical capsicum may provide immediate relief for patients with acute back pain [53]. There is no evidence to support the use of <u>lidocaine</u> patches in this setting.

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Herbal therapies – Though these treatments may be commonly used by patients, the
evidence to support the use of herbal therapies for low back pain is limited. (See <u>"Subacute</u>
and chronic low back pain: Nonpharmacologic and pharmacologic treatment", section on
<u>"Herbal therapies"</u>.)

PATIENT EDUCATION

Patient education is an important aspect of care. A 2015 systematic review of studies evaluating patient education for acute and subacute low back pain (eg, education on the benign nature and good prognosis of acute low back pain, advice to stay active) found moderate-quality evidence that, compared with usual care, patient education reduces acute low back pain-related primary care visits [54]. Our view is that patient education is necessary, but not sufficient, to result in improved outcomes.

Education should include information about the causes of back pain, favorable prognosis, generally minimal value of diagnostic testing, activity and work recommendations, and when to contact a clinician for follow-up [55]. (See 'Information for patients' below.)

PROGNOSIS

The prognosis for acute low back pain is excellent; only one-third of patients seek medical care at all [56]. Of those who present for care, 70 to 90 percent improve within seven weeks [57,58].

Recurrences are common, affecting up to 50 percent of patients within six months and 70 percent within 12 months [59,60]. Similar to the initial episode, recurrences have a favorable prognosis.

Some patients with acute low back pain will go on to develop chronic low back pain. Estimates of the percentage of patients who develop chronic back pain vary. In one prospective cohort study of patients with acute back pain seen in primary care, chronic back pain was diagnosed in 20 percent of patients within two years of their initial visit [59]. However, other studies have suggested only 5 to 10 percent of patients with acute low back pain go on to develop chronic low back pain [60-62].

Predictors of disabling chronic low back pain at one year include maladaptive pain coping

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behaviors, functional impairment, poor general health status, presence of psychiatric comorbidities, or nonorganic signs [63,64]. Maladaptive coping behaviors include fear avoidance (avoiding usual or recommended activities because of fear that they will cause worsening pain or hinder recovery) and catastrophizing (negative beliefs about pain or illness leading to patients imaging the worst possible outcome). (See "Evaluation of low back pain in adults", section on 'Physical examination'.)

Stratifying care in patients with acute low back pain based on risk assessment for chronicity is not of proven benefit. While studies that have assessed such an approach showed improved outcomes for disability and lost work time, the majority of patients in these studies (>80 percent) had subacute or chronic rather than acute low back pain [14,22,23].

PREVENTION

Exercise interventions may have some value in preventing recurrences of low back pain. (See "Exercise-based therapy for low back pain".)

There are few data to support other interventions, such as lumbar supports, smoking cessation, or weight loss, for the prevention of low back pain [26,65]. However, interventions such as smoking cessation or weight loss may be otherwise beneficial for health. There also is no evidence that spinal manipulation reduces the risk of recurrence of back pain [66]. Ergonomic interventions for the prevention of occupational low back pain are discussed elsewhere.

SOCIETY GUIDELINE LINKS

Links to society and government-sponsored guidelines from selected countries and regions around the world are provided separately. (See <u>"Society guideline links: Lower spine disorders"</u>.)

INFORMATION FOR PATIENTS

UpToDate offers two types of patient education materials, "The Basics" and "Beyond the Basics." The Basics patient education pieces are written in plain language, at the 5th to 6th grade reading level, and they answer the four or five key questions a patient might have about a given condition.

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These articles are best for patients who want a general overview and who prefer short, easy-to-read materials. Beyond the Basics patient education pieces are longer, more sophisticated, and more detailed. These articles are written at the 10th to 12th grade reading level and are best for patients who want in-depth information and are comfortable with some medical jargon.

Here are the patient education articles that are relevant to this topic. We encourage you to print or e-mail these topics to your patients. (You can also locate patient education articles on a variety of subjects by searching on "patient info" and the keyword(s) of interest.)

- Basics topics (see <u>"Patient education: Low back pain in adults (The Basics)"</u> and <u>"Patient education: Spinal stenosis (The Basics)"</u> and <u>"Patient education: Herniated disc (The Basics)"</u>)
- Beyond the Basics topic (see <u>"Patient education: Low back pain in adults (Beyond the Basics)"</u>)

SUMMARY AND RECOMMENDATIONS

- Most patients with acute low back pain improve regardless of specific management. We typically suggest nonpharmacologic therapy with superficial heat (<u>Grade 2C</u>). Massage, acupuncture, and spinal manipulation are other reasonable options depending upon patient preference and their cost and accessibility. There are no data demonstrating the superiority of one modality over another. Bed rest is not advised, and activity modification should be kept to a minimum. (See <u>'General approach to care'</u> above and <u>'Nonpharmacologic therapies'</u> above.)
- We do not refer most patients with acute low back pain for exercise or physical therapy.
 However, we selectively refer patients with risk factors for developing chronic low back pain (eg, poor functional or health status, psychiatric comorbidities) who may benefit from immediate physical education by a physical therapist, although this is unproven. (See 'Exercise and physical therapy' above.)
- For patients who prefer pharmacologic therapy or in whom nonpharmacologic approaches are
 inadequate, we suggest short-term (two to four weeks) treatment with a nonsteroidal
 antiinflammatory drug (NSAID) as initial therapy (<u>Grade 2C</u>). <u>Acetaminophen</u> is an acceptable
 alternative option in patients with a contraindication to NSAIDs, although it has limited efficacy.

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(See 'Initial therapy' above.)

- For patients with pain refractory to initial pharmacotherapy, we suggest the addition of a nonbenzodiazepine muscle relaxant (<u>Grade 2C</u>). In patients who cannot tolerate or have a contraindication to muscle relaxants, combining NSAIDs and <u>acetaminophen</u> is another option. (See <u>'Second-line therapy'</u> above.)
- Evidence to support the use of opioids and <u>tramadol</u> in acute low back pain is limited. We recommend reserving these agents for patients who do not have adequate relief from or have contraindications to other drugs (<u>Grade 1C</u>). If opioids are used, the duration of therapy should be limited to three to seven days. Tramadol should not be prescribed for more than two weeks. (See <u>'Refractory or severe pain'</u> above.)
- Drugs with limited or no evidence of effectiveness for acute low back pain include antidepressants, systemic glucocorticoids, antiepileptics, topical agents, and herbal therapies. (See <u>'Other medications'</u> above.)
- Patient education is an important aspect of care. Education should include information about
 the causes of back pain, favorable prognosis, generally minimal value of diagnostic testing,
 activity and work recommendations, and when to contact a clinician. (See <u>'Patient education'</u>
 above.)
- Patients who do not improve after four weeks of pharmacotherapy should be reassessed.
 Some patients with acute low back pain will go on to develop chronic low back pain. Predictors of disabling chronic low back pain at one year include maladaptive pain coping behaviors, functional impairment, poor general health status, presence of psychiatric comorbidities, or nonorganic signs. (See 'Prognosis' above.)
- Exercise interventions may have some value in preventing recurrences of low back pain. (See <u>'Prevention'</u> above.)

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GRAPHICS

Orally available nonopioid analgesic and nonsteroidal anti-inflammatory drugs (NSAIDs): Usual dosing for adults with pain or inflammation

Drug	Optional initial loading dose	Usual analgesic dose (oral)	Maximum dose per day (mg)	Selected characteristics and role in therapy
Para-aminophenol	derivative			
Acetaminophen* (paracetamol, APAP)	None	325 to 650 mg every 4 to 6 hours Or 1000 mg every 6 hours up to three times per day	3000 mg	 Effective for noninflammatory pain; may be opioid-sparing. Doses <2000 mg per day do not increase risk of serious GI complications. Does not alter platelet functioning. Can cause hepatotoxicity in chronic or acute overdose. Avoid or use a lower total daily dose (maximum 2000 mg per day) in older adults, patients at risk for hepatotoxicity (eg, regular alcohol use, malnourished) or with organ dysfunction. For short-term or one-time use, may use a total dose of up to 4000 mg per day in selected medically supervised patients. Interacts with warfarin (prolongs INR), isoniazid, and CYP450-inducing drugs (transaminitis). Warn patients about acetaminophen content in combination prescription (eg, oxycodone-acetaminophen) and OTC preparations.

NSAID agents

Applies to all nonselective NSAIDs:

- Effective for treatment of acute and chronic painful and inflammatory conditions. May decrease opioid requirements. Short-to-moderate-acting NSAIDs (eg, naproxen, ibuprofen) are preferred for most patients.
- Dose- and age-related risk of gastropathy.
- May cause or worsen renal impairment.
- Nonselective NSAIDs reversibly inhibit platelet functioning and can alter cardioprotective effects of aspirin.
- Avoid NSAIDs in patients with renal insufficiency (CrCl <60 mL/minute), GI bleeding, platelet dysfunction, reduced cardiac output, difficult-to-control hypertension, hypovolemia, hyponatremia, aspirin-sensitive asthma, or cirrhosis.
- Safety concerns of NSAID use in patients with, or at elevated risk for, cardiovascular disease or thrombotic

- events are addressed in a separate topic in UpToDate.
- Use with caution or avoid in patients receiving comedication with anticoagulants, systemic glucocorticoids, lithium, loop diuretics, and other interacting drugs. $^{\Delta}$
- Though some older adults may benefit from a brief course of NSAIDs at the lowest effective dose, use in most older adults should be avoided. Refer to the UpToDate topics on treatment of pain in older adults and older adults with organ dysfunction.

Salicylate (acety	rlated)			
Aspirin*	2600 mg	325 to 650 mg every 4 to 6 hours	4000 mg	 Standard for comparison, but now used infrequently for treatment of chronic pain and inflammation. Unlike other NSAIDs, irreversibly inhibits platelet functioning for life of the platelet (7 to 10 days).
Salicylates (non	acetylated)	!		
Diflunisal	1000 mg	500 mg every 8 to 12 hours	1500 mg	Applies to all nonacetylated salicylates:
Choline magnesium trisalicylate	1500 mg	750 mg every 8 to 12 hours	3000 mg	 No significant effect on platelet function at usual analgesic dose Less frequently associated with
Salsalate	1500 mg	750 to 1000 mg every 8 to 12 hours	3000 mg	GI bleeding than nonselective NSAIDs at usual analgesic doses Generally tolerated by adults with asthma at lower daily dose Diflunisal ≤1000 mg, choline magnesium trisalicylate and salsalate ≤2000 mg. Relatively slow onset. 500 mg dose of diflunisal has a comparable analgesic effect with 650 mg acetaminophen or aspirin.
Propionic acids (phenyl-propion	ic acid)		
Naproxen*	500 mg (naproxen base) 550 mg (naproxen sodium)	250 to 500 mg every 12 hours (naproxen base) 275 to 550 mg every 12 hours (naproxen sodium)	1250 mg acute, 1000 mg chronic (naproxen base) 1375 mg acute, 1100 mg chronic (naproxen sodium)	 A good choice for treatment of acut or chronic pain and inflammation in most patients if NSAID therapy is indicated. High doses (eg, 500 mg twice daily may have less cardiovascular toxicity than comparable doses of other NSAIDs. ◇ For the treatment of rheumatologic disorders, total daily dose may be increased to a maximum of 1500 m base (1650 mg naproxen sodium), when needed. Naproxen sodium has more rapid absorption and onset of effect than naproxen base.

Ibuprofen*	1600 mg	400 mg every 4 to 6 hours	3200 mg (acute), 2400 mg (chronic)	 200 to 400 mg dose has a comparable analgesic effect with 650 mg acetaminophen or aspirin. Short duration of effect. Useful alternative to naproxen in patients without cardiovascular risks.
Ketoprofen	100 mg	50 mg every 6 hours or 75 , mg every 8 hours	300 mg	 25 mg dose has a comparable analgesic effect to 400 mg ibuprofen. Short duration of effect.
Flurbiprofen	100 mg	50 to 100 mg every 6 to 12 hours	300 mg	Lozenge preparation available in some countries.
Oxaprozin	None	1200 mg once daily .	26 mg/kg up to 1800 mg (whichever is lower)	■ Long duration of effect.
Acetic acids (pyra	ano-indoleaceti	c acid)		
Diclofenac	75 or 100 mg (conventional tablets)	50 mg every 8 hours	150 mg Approved maximum daily dose in Canada is 100 mg	 Diclofenac is also available as a topical patch, solution, and gel for treatment of musculoskeletal pain and osteoarthritis of superficial joints, which may be useful in combination with or as an alternative to systemic NSAIDs. Refer to the UpToDate topic on initial treatment of osteoarthritis and separate table. Interacts with drugs that are strong inhibitors or inducers of CYP2C9 drug metabolism; use Lexi-Interact to determine specific interactions.
Etodolac	400 to 600 mg	Immediate release: 200 to 400 mg every 6 to 8 hours Extended release: 400 to 1000 mg once daily	Immediate release: 1000 mg Extended release: 1200 mg	 Relatively COX-2 selective at lower total daily dose of 600 to 800 mg. 200 mg dose has a comparable analgesic effect with 400 mg of ibuprofen.
Indomethacin	75 mg	Immediate release: 25 to 50 mg every 8 to 12 hours Controlled	150 mg	 Useful for treatment of acute gout and specific types of headache. Potent inhibitory effects on renal prostaglandin synthesis. More frequently associated with CNS

		release: 75 mg once or twice daily		side effects (eg, headache) compared with other NSAIDs. Carefully select and monitor patients to reduce risk of renal and cardiovascular toxicities.
Tolmetin	600 mg	400 to 600 mg every 8 hours	1800 mg	
Sulindac	300 mg	150 to 200 mg every 12 hours	400 mg	 More frequently associated with hepatic inflammation (idiosyncratic or with features of hypersensitivity) compared with other NSAIDs. Sulindac metabolites implicated in the formation of renal calculi; refer to the UpToDate topic on nonselective NSAID adverse effects. Prescribing should be limited to specialists with experience in treatment of chronic pain and inflammation.
Oxicams (enolic	acids)			
Meloxicam	7.5 mg (conventional tablets)	7.5 to 15 mg once daily	15 mg	 Long duration of effect; slow onset. Relatively COX-2 selective and minimal effect on platelet function at lower total daily dose of 7.5 mg. Rarely associated with serious cutaneous allergic reactions, including Stevens-Johnson syndrome.
Piroxicam	10 mg	10 to 20 mg once daily	20 mg	 A long-acting option for treatment of chronic pain and inflammation poorly responsive to other NSAIDs. Daily doses ≥20 mg increase risk of serious GI complications. Concurrent pharmacologic gastroprotection is suggested. Rarely associated with serious cutaneous allergic reactions, including Stevens-Johnson syndrome. Prescribing should be limited to specialists with experience in treatment of chronic pain and inflammation.
Fenamates (anth	ranilic acids)			
Meclofenamate (meclofenamic acid)	150 mg	50 mg every 4 to 6 hours	400 mg	 Alternate NSAID choice for treatment of acute or chronic pain, inflammation, and dysmenorrhea.

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				 Appears to be associated with higher incidence of GI disturbance (including diarrhea) compared with other nonselective NSAIDs.
Mefenamic acid	500 mg	250 mg every 6 hours	1000 mg	 Alternate NSAID choice for treatment of acute pain and dysmenorrhea. Duration of use not to exceed seven days (acute pain) or three days (dysmenorrhea). Anti-inflammatory efficacy is comparatively low. Not indicated for treatment of chronic pain or inflammation.
Nonacidic (naph	thylalkanone)	·.		
Nabumetone	1000 mg	500 to 750 mg every 8 to 12 hours or 1000 to 1500 mg once daily	2000 mg	 Moderate duration of effect; slow onset. Relatively COX-2 selective at lower total daily dose of 1000 mg or less. Minimal effect on platelet function at total daily dose of 1000 mg or less.
Selective COX-2 inh	nibitors [§]			
Celecoxib	400 mg	200 mg daily or 100 mg every 12 hours	400 mg	 Relative reduction in GI toxicity compared with nonselective NSAIDs. No effect on platelet function. Cardiovascular and renal risks are dose-related and appear similar to those of nonselective NSAIDs. Patients with indications for cardioprotection require aspirin supplement; individuals may require concurrent gastroprotection:
Etoricoxib (not available in the United States)	None	30 to 60 mg once daily	60 mg (chronic pain and inflammation) 120 mg (acute pain for up to eight days)	 May be associated with more frequent and severe dose-related cardiovascular effects (eg, hypertension) compared with nonselective and other COX-2 selective NSAIDs. Otherwise, risks and benefits as with celecoxib (see above).

GI: gastrointestinal; INR: international normalized ratio; CYP450: cytochrome P450; OTC: over-the-counter, available without prescription; CrCl: creatinine clearance; COX-2: cyclooxygenase, isoform 2; CYP2C9: cytochrome 2C9; CNS: central nervous system; SSRIs: selective serotonin reuptake inhibitors.

 Δ NSAIDs may interact with aspirin, warfarin, methotrexate, antihypertensives, serotonin reuptake inhibitor antidepressants (eg, SSRIs, cyclic antidepressants, venlafaxine), and other drugs. For specific interactions, use the Lexi-

^{*} Available without a prescription in the United States.

[¶] A list of CYP450-inducing drugs is available separately in UpToDate.

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Interact program included with UpToDate.

• Refer to the UpToDate topic on the cardiovascular effects of nonselective NSAIDs.

§ For additional information on gastroprotective strategies, including selective COX-2 inhibitors and other options, refer to the UpToDate topics on the overview of selective COX-2 inhibitors and on NSAIDs (including aspirin) and the primary prevention of gastroduodenal toxicity.

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- 1. Anon. Drugs for pain. Treatment guidelines from the Medical Letter; 2013. 11:31.
- 2. Castellsague J, Riera-Guardia N, Calingaert B, et al. Individual NSAIDs and upper gastrointestinal complications: A systematic review. Drug Saf 2012; 35:1127.
- 3. Lexicomp Online. Copyright © 1978-2019 Lexicomp, Inc. All Rights Reserved.

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