

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Migraine Therapy	P&T DATE:	12/8/2020
CLASS:	Neurological Disorders	REVIEW HISTORY (MONTH/YEAR)	12/19, 12/18, 9/17, 12/16, 9/15, 2/15, 2/10, 5/07
LOB:	MCL		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Migraine is a common disorder than can be debilitating for individuals suffering frequent attacks. While there is no cure for migraines, abortive agents are useful in relieving acute migraine attacks and the American Headache Society (AHS) and the American Academy of Neurology (AAN) have developed recommendations for pharmacotherapy options for migraine preventive therapies. This review will examine the management guidelines of migraines and the currently available anti-migraine agents and their coverage criteria.

Table 1: Available Anti-Migraine Agents (Current as of 12/2020)

ABORTIVE AGENTS				
Generic Name (Brand Name)	Available Strengths	Form Limits	Average cost per 30 days	Notes
SEROTONIN AGONISTS				
Rizatriptan Tablet (Maxalt)	5 mg Tablets	QL	\$6.89	Limit 9 tablets per month.
	10 mg Tablets		\$6.66	
	5 mg ODT		\$11.36	
	10 mg ODT		\$7.51	
Sumatriptan Tablet (Imitrex)	25 mg	QL	\$6.49	Limit 9 tablets per month.
	50 mg		\$5.22	
	100 mg		\$5.27	
Sumatriptan Nasal Spray (Imitrex)	5 mg/act	PA; QL	--	Reserved for patients ≥ 12 years of age and unable to take oral meds (including ODT). Max 6/month.
	20 mg/act		\$227.07	
Naratriptan Tablet (Amerge)	1 mg	ST; QL	\$23.53	Step therapy to treatment failure of either Sumatriptan or Rizatriptan in the last 365 days. Limit 9 tablets per month.
	2.5 mg		\$17.92	
Zolmitriptan Tablet (Zomig)	2.5 mg	ST; QL	\$31.55	Step therapy to treatment failure of either Sumatriptan or Rizatriptan in the last 365 days. Limit 9 tablets per month.
	5 mg		\$47.18	
	2.5 mg ODT		\$47.84	
	5 mg ODT		\$37.03	
Almotriptan Tablet (Axert)	6.25 mg	ST; QL	--	Step therapy to treatment failure of [1]Sumatriptan/Rizatriptan AND [2] Naratriptan/Zolmitriptan in the last 365 days. Limit 9 tablets per month.
	12.5 mg		\$258.32	

Eletriptan Tablet (Relpax)	20 mg	ST; QL	\$69.41	Step therapy to treatment failure of [1] Sumatriptan/Rizatriptan AND [2] Naratriptan/Zolmitriptan in the last 365 days. Limit 9 tablets per month.
	40 mg		\$54.30	
Sumatriptan (Imitrex, Zembrace, Onzetra Xsail)	4 mg/0.5 ml Injection	NF	--	Non-formulary
	6 mg/0.5 ml Injection		\$96.34	
	11 mg Nasal powder		--	
Frovatriptan Tablet (Frova)	2.5mg	NF	--	Non-formulary

H3L-ANALGESIC, NON-SALICYLATE, BARBITURATE, XANTHINE COMBINATION

Butalbital/Acetaminophen/ Caffeine 50 mg/300 mg/ 40mg (Fioricet)	Capsules	NF	\$29.95	
Butalbital/Acetaminophen/ Caffeine 50 mg/325 mg/ 40mg (Esgic, Alagesic LQ, Vanatol LQ)	Capsules	NF	--	Limit 30 units per month. Capsules are non-formulary
	Tablets	QL	\$9.30	
	Liquid	NF		

H3M-NARCOTIC, NON-SALICYLATE ANALGESIC, BARBITURATE, XANTHINE

Butalbital/Acetaminophen/ Caffeine/Codeine 50 mg/300 mg/ 40 mg/30 mg	Capsule	NF		
Butalbital/Acetaminophen/ Caffeine/Codeine 50 mg/325 mg/ 40 mg/30 mg	Capsule	QL	\$28.10	Reserved for patients ≥12 years of age. Limit 30 units per month.

H3O-ANALGESIC, SALICYLATE, BARBITURATE, & XANTHINE CMB

Butalbital/Aspirin/Caffeine 50 mg/325 mg/40 mg (Fiorinal)	Capsule	QL	\$ 24.12	Limit 30 units per month.
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H3R-NARCOTIC AND SALICYLATE ANALGESIC, BARBITURATE & XANTHINE COMBINATION

Butalbital/Aspirin/Caffeine/ Codeine 50 mg/325 mg/40 mg/ 30mg (Fiorinal with Codeine)	Capsule	NF	\$39.14	
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ERGOT ALKALOIDS/ OTHER

Ergotamine Tartrate/Caffeine (Cafergot)	1 mg/100 mg Tablets	QL	\$291.43	Limit 30 units per month.
	2 mg/100 mg Suppository		--	
Ergotamine Tartrate (Ergomar)	2 mg SL Tablet	QL	-	Limit 30 units per month.

Isometheptene/ Dichloralphen/ Acetaminophen 65 mg/100 mg/ 325 mg	Capsule	NF	\$78.68	
PROPHYLACTIC AGENTS				
GENERIC NAME (BRAND NAME)	USUAL DOSE	FORM LIMITS	AVG COST PER 30 DAYS	NOTES
MIGRAINE-PREVENTIVE AGENTS				
Amitriptyline	25-150 mg per day	--	\$15.28	--
Atenolol	100 mg per day	--	\$3.45	--
Divalproex/Valproic Acid	400-1,000 mg per day	--	\$67.22	--
Metoprolol Tartrate	47.5-200 mg per day	--	\$3.39	--
Propranolol	120-240 mg per day	--	\$18.24	--
Timolol	10-30 mg per day	--	--	--
Topiramate	25-200 mg per day	--	\$11.63	--
Venlafaxine	150 mg ER per day	--	--	--
OnabotulinumtoxinA Injection (Botox)	100 units	PA, ST	--	[A] For patients age 18 years or older [B] Must be prescribed by a Neurologist [C] ALL of the following criteria must be met: (1) ≥ 15 or more days per month for ≥ 3 months (2) ≥ 4 hours a day or longer duration, as indicated by 5 or more attacks with ALL of the following: (a) Headache symptoms, as indicated by 2 or more of the following: <ul style="list-style-type: none"> • Aggravation by or causing avoidance of routine physical activity • Moderate or severe pain intensity • Pulsating quality • Unilateral location (b) Migraine-associated symptoms, as indicated by 1 or more of the following: <ul style="list-style-type: none"> • Nausea or vomiting • Photophobia and phonophobia (c) Other potential causes of headaches have been excluded. (3) Use 3 different preventive medications at therapeutic dose (eg, beta-blocker, calcium channel blocker, tricyclic antidepressant, anticonvulsant) unless therapy has been ineffective or not tolerated for trial of at least 3 month each. (4) No neuromuscular disease (eg, myasthenia gravis)
	200 units		\$1,442.40	
Erenumab-aooe Auto-Injector (Aimovig)	70 mg/ 1 ml	PA, ST, QL	\$590.62	Reserved for patients who have failed 6 months of therapy with Botox and are 18 years of age or older. Must be prescribed by a neurologist. Limit 1 injection per month.
	140 mg Dose		\$592.41	
Fremanezumab (Ajovy)	225 mg/1.5 ml	PA, ST, QL	\$586.50	Reserved for patients who have failed 6 months of therapy with Botox and are 18 years of age or older. Must be prescribed by a neurologist. Limit 3 injections per 3 months.

Galcanezumab (Emgality)	120 mg/ml	PA, ST, QL	\$594.65	Reserved for patients who have failed 6 months of therapy with Botox and are 18 years of age or older. Must be prescribed by a neurologist. Limit 1 injection per month.
PREVENTIVE AGENTS W/ NSAIDS				
Ibuprofen	200 mg twice daily	-	\$5.67	--
Naproxen	500-1,000 mg per day	-	\$7.17	--
NF = Non-Formulary; PA = Prior Authorization Required; QL = Quantity Limit				

⊕ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Serotonin Agonists

Sumatriptan Tablet (Imitrex), Sumatriptan Nasal Spray (Imitrex)*, Rizatriptan Tablet (Maxalt)

- Coverage Criteria:** None
- Limits:** Limit 9 units per 30 days.
- Required Information for Approval:** None
- Other Notes:** *Sumatriptan nasal spray is reserved for patients ≥12 years of age with documented inability to swallow tablets/capsules (including ODT tablets). Limited to 6 units per 30 days. For frequent HA >2 attacks/month, prophylaxis with Topamax/Depakote/beta blocker may be considered.
 - **Onzetra Xsail, Zembrace Symtouch are Non-Formulary**

Naratriptan (Amerge) Tablet, Zolmitriptan (Zomig) Tablet/ODT

- Coverage Criteria:** Step therapy to treatment failure of either Sumatriptan or Rizatriptan in the last 365 days.
- Limits:** Limit 9 units per 30 days.
- Required Information for Approval:** Prescription history of Sumatriptan or Rizatriptan OR documented intolerance to Sumatriptan or Rizatriptan.
- Other Notes:** None.

Eletriptan (Relpax), Almotriptan (Axert) Tablet

- Coverage Criteria:** Step therapy to treatment failure of [1] Sumatriptan/Rizatriptan AND [2] Naratriptan or Zolmitriptan in the last 365 days. For frequent headaches >2 per month, prophylaxis with Topamax, Depakote, or beta blockers may be considered. Restricted to 9 tabs/30 days.
- Limits:** Limit 9 units per 30 days.
- Required Information for Approval:** Prescription history of [1] Sumatriptan or Rizatriptan and [2] Naratriptan or Zolmitriptan **OR** documented intolerance to Sumatriptan/Rizatriptan and Naratriptan or Zolmitriptan.
- Other Notes:** None
- Non-Formulary:** Sumatriptan Injection, Frovatriptan

Butalbital Combination Agents

Butalbital/APAP/Caffeine (Fioricet), Butalbital/APAP/Caffeine/Codeine, Butalbital/Aspirin/Caffeine (Fiorinal)

- Coverage Criteria:** None
- Limits:** Limit 30 tablets/capsules per 30 days.
- Required Information for Approval:** None
- Other Notes:** Butalbital/APAP/Caffeine/Codeine is restricted to patients ≥12 years of age.

Ergot Alkaloids/Other

Ergotamine Tartrate/Caffeine, Ergotamine Tartrate, Isometh/Dichlph/Acetaminophen

- Coverage Criteria:** None
- Limits:** Limit 30 tablets/capsules per 30 days.
- Required Information for Approval:** None
- Other Notes:** None

Migraine Prophylactic Agents

Amitriptyline, Divalproex, Metoprolol, Propranolol, Topiramate, Ibuprofen, Naproxen

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** None
- Other Notes:** None

OnabotulinumtoxinA (Botox) Injection

- Coverage Criteria:** ALL of the following must be met:
 - [A] For patients age 18 years or older
 - [B] Must be prescribed by a Neurologist
 - [C] **ALL** of the following criteria must be met:
 - (1) ≥ 15 or more days per month for ≥ 3 month
 - (2) ≥ 4 hours a day or longer duration, as indicated by 5 or more attacks with **ALL** of the following:
 - (a) Headache symptoms, as indicated by 2 or more of the following: *Aggravation by or causing avoidance of routine physical activity, or *Moderate or severe pain intensity, or *Pulsating quality, or *Unilateral location
 - (b) Migraine-associated symptoms, as indicated by 1 or more of the following: *Nausea or vomiting, or *Photophobia and phonophobia
 - (c) Other potential causes of headaches have been excluded
 - (3) Use 3 different preventive medications at therapeutic dose (eg, beta-blocker, Calcium channel blocker, tricyclic antidepressant, anticonvulsant) unless therapy has been ineffective or not tolerated for trial of at least 3 month each
 - (4) No neuromuscular disease (eg, myasthenia gravis)
- Limits:** 1 injection per 3 months
- Required Information for Approval:** Clinical documentations, chart notes, and pharmacy fill history indicating all of the criteria listed above are met.
- Other Notes:** None

Erenumab-aooe (Aimovig) Auto-Injector

- Coverage Criteria:** PA required. Reserved for patients who have failed 6 months of therapy with Botox and are 18 years of age or older. Must be prescribed by a Neurologist.
- Limits:** 1 injection per month.
- Required Information for Approval:** Clinical documentations, chart notes, and pharmacy fill history indicating all of the criteria listed above are met.
- Other Notes:** None

Fremanezumab (Ajovy) Injection

- Coverage Criteria:** PA required. Reserved for patients who have failed 6 months of therapy with Botox and are 18 years of age or older. Must be prescribed by a Neurologist.
- Limits:** 3 injections per 3 months.
- Required Information for Approval:** Clinical documentations, chart notes, and pharmacy fill history indicating all of the criteria listed above are met.
- Other Notes:** None

Galcanezumab (Emgality) Injection

- Coverage Criteria:** PA required. Reserved for patients who have failed 6 months of therapy with Botox and are 18 years of age or older. Must be prescribed by a Neurologist.
- Limits:** 1 injection per month.

- Required Information for Approval:** Clinical documentations, chart notes, and pharmacy fill history indicating all of the criteria listed above are met.
- Other Notes:** None

CLINICAL JUSTIFICATION

Frequent migraine attacks are not only disabling and lead to a poor quality of life, but frequent use of abortive therapies can lead to chronic migraines. For this reason, patients experiencing more than 2 headaches per month¹ or patients with headaches lasting more than 2 days duration are candidates for migraine prophylaxis.^{2,3} The 2012 AHS/AAN Guidelines recommend the following medications as migraine prophylaxis therapies: divalproex/valproic acid, metoprolol, propranolol, and topiramate.⁴ 2013 AHS/AAN Guideline updates include timolol as one of the agents for migraine prevention.¹⁶ NSAID use for migraine prevention has shown modest to significant benefit—particularly for naproxen and ibuprofen.⁵ The time it takes to observe the therapeutic benefits of migraine prophylaxis varies between individuals, so international guidelines suggest a minimum of a two to three month trial.⁶

In regards to abortive therapies, serotonin agonists are similar in migraine relief but some are faster-acting than others. Sumatriptan formulations are the fastest-acting. Almotriptan, Eletriptan, Rizatriptan, and Zolmitriptan are intermediate-acting while Frovatriptan and Naratriptan have the slowest onset. Frovatriptan costs 3 times more than Naratriptan tablets per fill. With similar onset times and a limited cost-benefit ratio, Frovatriptan will remain non-formulary. Sumatriptan injections are marketed to have the fastest onset (10 minutes vs <30 minutes for sumatriptan tablets). However, its cost-benefit ratio is not cost-effective since sumatriptan injections cost approximately 10 times more than Sumatriptan tablets. For this reason, sumatriptan injections are non-formulary. Zembrace (Sumatriptan SQ injections) comes in a 3mg/0.5 mL pre-filled auto-injector that can have a maximum daily dose of 12 mg, equating to a cost of almost 90 times more than Sumatriptan tablets, hence as there are other non-oral formulations available and there is not a distinguished cost-effectiveness present with Zembrace, it will also remain non-formulary.⁷

Sumatriptan nasal spray is currently on formulary for patients who have a documented inability to use tablets/capsules (including ODT). This allows for an alternate formulation besides oral agents for acute migraine therapy. Onzetra Xsail is a new formulation of Sumatriptan that also acts via the nasal passageway but is administered via first piercing one of the 11 mg nosepieces to release Sumatriptan from the capsule, followed by attaching both nosepieces from the device body into each nostril so it makes a tight seal, then rotating the whole device so the mouthpiece could be placed into the mouth, and finally having the patient forcefully blow through the mouthpiece to deliver the Sumatriptan powder into the nasal cavity.⁸ The patient would then need to repeat all the above steps a second time to obtain a total recommended dose of 22 mg per administration. As there is already a Sumatriptan nasal formulation that is on formulary for half the cost per fill and uses a method of administration that is not completely new to patients, Onzetra Xsail will remain non-formulary.

In the latest 2019 American Headache Society consensus statement, CGRP inhibitors are a suitable option for the prevention of migraines. CGRP inhibitors should only be tried after an inability to tolerate or inadequate response with other agents (including onabotulinumtoxinA). Because of long-term safety evidence and efficacy, onabotulinumtoxinA should still be tried before using any CGRP inhibitor.³⁴

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REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Topiramate review 5-07.doc	5/2007	Allen Shek, PharmD
Updated Policy	Triptan_utilization_review_2-16-10.docx	2/2010	Allen Shek, PharmD
Updated Policy	Opioid Coverage Policy 2015-02-17.docx	2/2015	Jonathan Szkotak, PharmD
Updated Policy	HPSJ Coverage Policy – Neurologic – Migraines 2015-02.docx	2/2015	Jonathan Szkotak, PharmD
Updated Policy	HPSJ Coverage Policy – Neurologic – Migraines 2015-09.docx	9/2015	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy – Neurologic – Migraines 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy – Neurologic – Migraines 2017-09.docx	9/2017	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy – Neurologic – Migraines 2018-12.docx	12/2018	Matthew Garrett, PharmD
Updated Policy	HPSJ Coverage Policy – Neurologic – Migraines 2019-12.docx	12/2019	Matthew Garrett, PharmD
Updated Policy	HPSJ Coverage Policy – Neurologic – Migraines 2020-12.docx	12/2020	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy