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OHSU Drug Effectiveness Review Project Summary Report – Migraine Treatment and Prevention

Date of Review: May 2019

Date of Last Review: Triptans: March 2016; Beta-blockers: May 2015; Botulinum Toxins: September 2018; Antiepileptics: January 2019
Literature Search: 10/01/2018-03/18/2019

Current Status of PDL Class:
See **Appendix 1**.

Research Questions:

1. Is there new comparative evidence evaluating treatments or preventative therapies for migraines based on important outcomes (e.g., headache frequency, acute migraine medication use, reduction in number of migraines per month)?
2. Is there new comparative harms data for treatments of migraines (e.g., withdrawals due to adverse events, severe adverse events)?
3. Are there certain sub-populations (based on age, gender, ethnicity, or comorbidities) in which certain migraine treatments are more effective or cause less harm?
4. Is there any comparative evidence between traditional migraine therapies (triptans, botulinum toxins, antiepileptics and beta-blockers) and newer CGRP treatments for migraines?

Conclusions:

- The Drug Effectiveness Review Project (DERP) provided all of evidence for this review. There was very low or low quality of evidence for most outcome comparisons. All but one outcome with moderate quality evidence found no difference between therapies used for migraine treatment or prevention.
    - There is moderate evidence that preventative therapy with propranolol (40-160 mg) was associated with a greater reduction in rescue medication use compared to topiramate 200 mg in adult patients with episodic migraine.
- There is insufficient comparative evidence for efficacy or harms for traditional migraine therapies compared to newer calcitonin gene-related peptide (CGRP) therapies.

Recommendations:

- No changes to the preferred drug list (PDL) are recommended based on review of the evidence for prevention and treatment of migraine.
- After evaluation of comparative cost in executive session, make sumatriptan succinate syringe and zolmitriptan tablets, rapid tablets and nasal spray preferred.

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Summary of Prior Reviews and Current Policy

- A review done in September 2018 updated the prior authorization (PA) criteria to incorporate Guideline Note 42 amendments allowing for the use of chemodenervation (botulinum toxin) for the treatment of chronic migraine. This policy that went into effect October 2018 which authorized coverage of botulinum toxins for patients with migraine headache that have failed treatment with anticonvulsants, tricyclics and beta-blockers. Renewal of botulinum toxin therapy requires a 7 day or more reduction in headaches from baseline headache frequency. A review in March of 2016 found all triptan formulations to be superior to placebo for migraine relief. A sumatriptan review demonstrated that the subcutaneous injection to be the most effective route of administration. The recommendation was to include an oral, nasal and injectable triptan formulation on the PDL. Preferred triptans are sumatriptan (all formulations) and oral naratriptan. All triptans have quantity limits to ensure appropriate use. Current PA criteria for topiramate requires a 90-day trial with evidence of efficacy for continued use. Overall utilization for the class has high PDL adherence (92% or greater) with minimal financial impact to the Oregon Health Plan (OHP). There have been no recent new recommendations for the use of antiepileptic or beta-blockers for the treatment or prevention of migraine.

Methods:

The February 2019 drug class report on Pharmacological Options for the Prevention and Treatment of Chronic and Episodic Migraines by the Drug Effectiveness Review Project (DERP) at the Pacific Northwest Evidence-based Practice Center at the Oregon Health & Science University (OHSU) was used to inform recommendations for this drug class.

The original report is available to Oregon Pharmacy and Therapeutics Committee members upon request. An executive summary report is publically available in the agenda packet and on the DURM website.

The purpose of the DERP reports is to make available information regarding the comparative clinical effectiveness and harms of different drugs. DERP reports are not usage guidelines, nor should they be read as an endorsement of or recommendation for any particular drug, use, or approach. OHSU does not recommend or endorse any guideline or recommendation developed by users of these reports.

Summary Findings:

An analysis of the treatment and prevention of migraine was done by DERP in February 2019.[1] A search ending in October 2018 identified 19 randomized clinical trials in adults and children or adolescents for the prevention and treatment of chronic and episodic migraine. Patients with non-migraine headache types (e.g., tension, cluster, and secondary headaches) were not included. Drugs included from the five following classes are included: anticonvulsants, antidepressants, beta-blockers, triptans, and other (**Table 1**).[1] The calcitonin gene-related peptide (CGRP) biologic medications for migraine were excluded, as they were evaluated in a previous analysis by DERP. Eight of the trials were graded as fair or good quality and 12 were considered poor quality. Prevention of migraine was the focus of 16 of the studies and 3 studies (all of low or very low quality), evaluated the treatment of acute migraine. Chronic migraine is defined as 15 or more days of headache per month, lasting at least 3 months, and having migraine features at least 8 days per month. Episodic migraine is considered a subclassification of migraine that is not considered chronic. The main outcomes of interest were migraine events, pain, other symptoms and adverse events.

Table 1. Migraine Treatments Included in the DERP Report[1]

Therapeutic Class	Drug or Drug Combination
Anticonvulsants	• Carbamazepine (e.g., Carbatrol, Epitol, Equetro, Tegretol) • Divalproax (e.g., Depakote) • Topiramate (e.g., Qudexy XR, Topamax, Trokendi XR)

	• Valproic acid and derivatives (e.g., Depakene)
Antidepressants	• Amitriptyline (generic) • Venlafaxine (e.g., Depakene)
Beta-blockers	• Atenolol (e.g., Tenormin) • Metoprolol (e.g., Lopressor) • Nadolol (e.g., Corgard) • Nebivolol (e.g., Bystolic) • Propranolol (e.g., Hemangeol, Inderal, InnoPran XL) • Timolol (e.g., Betimol, Istalol, Timoptic)
Tripatans	• Almotriptan (Axert) • Eletriptan (Relpax) • Frovatriptan (Frova) • Naratriptan (Amerge) • Rizatriptan (Maxalt, Maxalt-MLT) • Sumatriptan (e.g., Imitrex, Onzetra Xsail, Zembrace SymTouch) • Zolmitriptan (Zomig, Zomig-ZMT)
Other	• Dihyrdoergotamine (D.H.E. 45, Migranal) • Ergotamine (Ergomar) • OnabotulinumtoxinA (Botox)
Combination Therapies	• Acetaminophen, aspirin, and caffeine (generic) • Acetaminophen, caffeine, and isometheptene and dichloraphenazone (generic) • Acetaminophen, isometheptene, and dichloralphenazone (generic) • Ergotamine and caffeine (Cafergot, Migergot) • Sumatriptan and naproxen (Treximet)

Chronic Migraines

Four studies evaluated the treatment of chronic migraines.[1] Efficacy and harms comparisons of treatments for chronic migraines demonstrated similar efficacy and harms data, all based on very low or low quality evidence. There was insufficient evidence for outcomes related to the prevention of chronic migraine in children or treatment of chronic migraine in adults, adolescents or children (all very low or low quality of evidence).

Episodic Migraines

Thirteen studies were used for the analysis of episodic migraine.[1] Studies were divided into treatment and prevention groups. There was moderate quality evidence for three outcomes for the *prevention* of episodic migraines: number of migraines per month, withdrawals due to adverse events and days with acute migraine medication use per month (**Table 2**). The outcomes were downgraded for unclear methods of randomization, allocation concealment and conflicts of interest.

Table 2. Therapies for the Prevention of Episodic Migraines in Adults[1]

Comparison	Outcome	Findings*	Quality of Evidence
Topiramate (25 mg to 200 mg) vs. amitriptyline (10-150 mg/day)	Migraine days per month	Trial 1 – Topiramate: -2.6 days Amitriptyline: -2.7 days P=0.87 Trial 2 – Topiramate: 0.65 Amitriptyline: 0.91 P>0.05 *No significant difference*	Moderate
	Withdrawals due to adverse events	Trial 1 – Topiramate: 19.7% Amitriptyline: 22.5% P=0.52 Trial 2- Topiramate: 8.3% Amitriptyline: 14.2% P=0.50 *No significant difference*	Moderate
Topiramate (25 mg to 200 mg/day) vs. Propranolol (40 mg to 160 mg/day)	Days with acute migraine medication use per month	Topiramate 100 mg: -1.5 Topiramate 200 mg: -0.9 Propranolol: -1.6 P=0.74 (topiramate 100 vs. propranolol) P=0.02 (topiramate 200 vs. propranolol) *Propranolol associated with a greater reduction in rescue medication use compared to topiramate 200 mg but not compared to topiramate 100 mg*	Moderate
* Confidence intervals were not provided			

Mixed Migraine Populations – chronic and episodic

Two studies analyzed the prevention of mixed migraines (chronic and episodic).[1] Comparisons in adults were found to be of very low quality, therefore, conclusions could not be drawn. Trials done in children and adolescents were found to have moderate quality of evidence for the comparison of topiramate versus amitriptyline (**Table 3**).

Table 3. Outcomes for Therapies used for Mixed Migraine[1]

Comparison	Outcome	Findings*	Quality of Evidence
Topiramate (2 mg/kg/day) vs. amitriptyline (1 mg/kg/day)	Migraine days per month	Absolute change: Topiramate: -6.7 days Amitriptyline: -6.7 days MD -0.1 (98.3% CI, -1.7 to 1.5) *No significant difference*	Moderate
	Percentage with at least 50% reduction in the number of migraine days per month	Topiramate: 55% Amitriptyline: 52% Adjusted OR 1.14 P>0.05 *No significant difference*	Moderate
	Serious adverse events	Topiramate: 4 Amitriptyline: 6 P>0.05 *No significant difference*	Moderate
	Withdrawals due to adverse events	Topiramate: 22% Amitriptyline: 20% P=0.76 *No significant difference*	Moderate
* Confidence intervals were not provided			

References:

1. Suggested citation: Lazur B, Harrod C. *Pharmacological options for the prevention and treatment of chronic and episodic migraines.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University; 2019.

Appendix 1: Current Preferred Drug List

Triptans, Nasal

Generic	Brand	Form	PDL
sumatriptan	IMITREX	SPRAY	Y
sumatriptan	SUMATRIPTAN	SPRAY	Y
sumatriptan	ONZETRA	AER POW	
succinate	XSAIL	BA	N
zolmitriptan	ZOMIG	SPRAY	N

Triptans, Oral

Generic	Brand	Form	PDL
sumatriptan succinate	IMITREX	TABLET	Y
sumatriptan succinate	SUMATRIPTAN SUCCINATE	TABLET	Y
naratriptan HCl	AMERGE	TABLET	Y
naratriptan HCl	NARATRIPTAN	TABLET	Y
naratriptan HCl	NARATRIPTAN HCL	TABLET	Y
zolmitriptan	ZOLMITRIPTAN ODT	TAB RAPDIS	N
zolmitriptan	ZOMIG ZMT	TAB RAPDIS	N
zolmitriptan	ZOLMITRIPTAN	TABLET	N
zolmitriptan	ZOMIG	TABLET	N
rizatriptan benzoate	MAXALT MLT	TAB RAPDIS	N
rizatriptan benzoate	RIZATRIPTAN	TAB RAPDIS	N
rizatriptan benzoate	MAXALT	TABLET	N
rizatriptan benzoate	RIZATRIPTAN	TABLET	N
almotriptan malate	ALMOTRIPTAN MALATE	TABLET	N
frovatriptan succinate	FROVA	TABLET	N
frovatriptan succinate	FROVATRIPTAN SUCCINATE	TABLET	N
eletriptan hydrobromide	ELETRIPTAN HBR	TABLET	N
eletriptan hydrobromide	RELPAX	TABLET	N
sumatriptan succ/naproxen sod	SUMATRIPTAN SUCC-NAPROXEN SOD	TABLET	N
sumatriptan succ/naproxen sod	TREXIMET	TABLET	N

Triptans, Subcutaneous

Generic	Brand	Form	PDL
sumatriptan succinate	IMITREX	CARTRIDGE	Y
sumatriptan succinate	SUMATRIPTAN SUCCINATE	CARTRIDGE	Y
sumatriptan succinate	ALSUMA	PEN INJCTR	Y
sumatriptan succinate	IMITREX	PEN INJCTR	Y
sumatriptan succinate	SUMATRIPTAN SUCCINATE	PEN INJCTR	Y

sumatriptan succinate	IMITREX	VIAL	Y
sumatriptan succinate	SUMATRIPTAN SUCCINATE	VIAL	Y
sumatriptan succinate	SUMAVEL DOSEPRO	NDL FR INJ	N
sumatriptan succinate	ZEMBRACE SYMTOUCH	PEN INJCTR	N
sumatriptan succinate	SUMATRIPTAN SUCCINATE	SYRINGE	N

Botulinum Toxins

Generic	Brand	Form	PDL
abobotulinumtoxinA	DYSPORT	VIAL	
incobotulinumtoxinA	XEOMIN	VIAL	N
incobotulinumtoxinA	XEOMIN	VIAL	
onabotulinumtoxinA	BOTOX	VIAL	
onabotulinumtoxinA	BOTOX COSMETIC	VIAL	
onabotulinumtoxinA	BOTOX COSMETIC	VIAL	
rimabotulinumtoxinB	MYOBLOC	VIAL	

Antiepileptics

Generic	Brand	Form	PDL	Carveout
carbamazepine	CARBAMAZEPINE	ORAL SUSP	Y	
carbamazepine	TEGRETOL	ORAL SUSP	Y	
carbamazepine	CARBAMAZEPINE	TAB CHEW	Y	
carbamazepine	CARBAMAZEPINE ER	TAB ER 12H	Y	
carbamazepine	TEGRETOL XR	TAB ER 12H	Y	
carbamazepine	CARBAMAZEPINE	TABLET	Y	
carbamazepine	EPITOL	TABLET	Y	
carbamazepine	TEGRETOL	TABLET	Y	
divalproex sodium	DEPAKOTE SPRINKLE	CAP DR SPR	Y	Y
divalproex sodium	DIVALPROEX SODIUM	CAP DR SPR	Y	Y
divalproex sodium	DEPAKOTE ER	TAB ER 24H	Y	Y
divalproex sodium	DIVALPROEX SODIUM ER	TAB ER 24H	Y	Y
divalproex sodium	DEPAKOTE	TABLET DR	Y	Y
divalproex sodium	DIVALPROEX SODIUM	TABLET DR	Y	Y
topiramate	TOPAMAX	TABLET	Y	
topiramate	TOPIRAMATE	TABLET	Y	
valproic acid	DEPAKENE	CAPSULE	Y	Y
valproic acid	VALPROIC ACID	CAPSULE	Y	Y
valproic acid (as sodium salt)	DEPAKENE	SOLUTION	Y	Y
valproic acid (as sodium salt)	VALPROIC ACID	SOLUTION	Y	Y
topiramate	TROKENDI XR	CAP ER 24H	N	

topiramate	QUDEXY XR	CAP SPR 24	N
topiramate	TOPIRAMATE ER	CAP SPR 24	N
topiramate	TOPAMAX	CAP SPRINK	N
topiramate	TOPIRAMATE	CAP SPRINK	N

Beta-Blockers

Generic	Brand	Form	PDL
atenolol	ATENOLOL	TABLET	Y
atenolol	TENORMIN	TABLET	Y
metoprolol succinate	METOPROLOL SUCCINATE	TAB ER 24H	Y
metoprolol succinate	TOPROL XL	TAB ER 24H	Y
metoprolol tartrate	LOPRESSOR	TABLET	Y
metoprolol tartrate	METOPROLOL TARTRATE	TABLET	Y
propranolol HCl	PROPRANOLOL HCL	TABLET	Y
metoprolol succinate	KAPSPARGO SPRINKLE	CAP SPR 24	N
nadolol	CORGARD	TABLET	N
nadolol	NADOLOL	TABLET	N
nebivolol HCl	BYSTOLIC	TABLET	N
propranolol HCl	INDERAL XL	CAP ER 24H	N
propranolol HCl	INNOPRAN XL	CAP ER 24H	N
propranolol HCl	INDERAL LA	CAP SA 24H	N
propranolol HCl	PROPRANOLOL HCL ER	CAP SA 24H	N
propranolol HCl	HEMANGEOL	SOLUTION	N
propranolol HCl	PROPRANOLOL HCL	SOLUTION	N
timolol maleate	BLOCADREN	TABLET	N
timolol maleate	TIMOLOL MALEATE	TABLET	N

Other Analgesics

Generic	Brand	Route	Form	PDL
butalb/acetaminophen/caffeine	BUTALBITAL-ACETAMINOPHEN-CAFFE	PO	CAPSULE	N
butalb/acetaminophen/caffeine	CAPACET	PO	CAPSULE	N
butalb/acetaminophen/caffeine	ESGIC	PO	CAPSULE	N
butalb/acetaminophen/caffeine	FIORICET	PO	CAPSULE	N
butalb/acetaminophen/caffeine	ZEBUTAL	PO	CAPSULE	N
butalb/acetaminophen/caffeine	VANATOL LQ	PO	SOLUTION	N
butalb/acetaminophen/caffeine	VANATOL S	PO	SOLUTION	N
butalb/acetaminophen/caffeine	AMERICET	PO	TABLET	N
butalb/acetaminophen/caffeine	BUTALBITAL-ACETAMINOPHEN-CAFFE	PO	TABLET	N
butalb/acetaminophen/caffeine	ESGIC	PO	TABLET	N
butalb/acetaminophen/caffeine	QUALA-CET	PO	TABLET	N

butalbital/acetaminophen	BUTALBITAL-ACETAMINOPHEN	PO	CAPSULE	N
butalbital/acetaminophen	ALLZITAL	PO	TABLET	N
butalbital/acetaminophen	BUPAP	PO	TABLET	N
butalbital/acetaminophen	BUTALBITAL-ACETAMINOPHEN	PO	TABLET	N
butalbital/acetaminophen	MARTEN-TAB	PO	TABLET	N
butalbital/acetaminophen	REPAN-CF	PO	TABLET	N
butalbital/aspirin/caffeine	BUTALBITAL-ASPIRIN-CAFFEINE	PO	CAPSULE	N
butalbital/aspirin/caffeine	FIORINAL	PO	CAPSULE	N
butalbital/aspirin/caffeine	BUTALBITAL-ASPIRIN-CAFFEINE	PO	TABLET	N
acetaminophen/caffeine	EXCEDRIN TENSION HEADACHE	PO	TABLET	
acetaminophen/caffeine	TENSION HEADACHE	PO	TABLET	
acetaminophen/caffeine	TENSION HEADACHE RELIEF	PO	TABLET	
ASA/acetaminophen/caffeine/cal	SUPAC	PO	TABLET	
aspirin/acetaminophen/caffeine	EXCEDRIN EXTRA STRENGTH	PO	TABLET	
aspirin/acetaminophen/caffeine	EXCEDRIN MIGRAINE	PO	TABLET	
aspirin/acetaminophen/caffeine	EXTRA PAIN RELIEF	PO	TABLET	
aspirin/acetaminophen/caffeine	HEADACHE PAIN	PO	TABLET	
aspirin/acetaminophen/caffeine	HEADACHE RELIEF	PO	TABLET	
aspirin/acetaminophen/caffeine	MIGRAINE FORMULA	PO	TABLET	
aspirin/acetaminophen/caffeine	MIGRAINE RELIEF	PO	TABLET	
aspirin/acetaminophen/caffeine	PAIN RELIEVER PLUS	PO	TABLET	
aspirin/caffeine	AA & C	PO	TABLET	
aspirin/caffeine	BACK-BODY PAIN RELIEVER	PO	TABLET	
dihydroergotamine mesylate	D.H.E.45	IJ	AMPUL	
dihydroergotamine mesylate	DIHYDROERGOTAMINE MESYLATE	IJ	AMPUL	
dihydroergotamine mesylate	DIHYDROERGOTAMINE MESYLATE	NS	SPRAY/PUMP	
dihydroergotamine mesylate	MIGRANAL	NS	SPRAY/PUMP	
ergotamine tartrate	ERGOMAR	SL	TAB SUBL	
ergotamine tartrate/caffeine	CAFERGOT	PO	TABLET	
ergotamine tartrate/caffeine	MIGERGOT	RC	SUPP.RECT	

Appendix 2: Search History

Database(s): **Ovid MEDLINE(R)** 1946 to March Week 3 2019

Search Strategy:

#	Searches	Results
1	sumatriptan.mp. or Sumatriptan/	2938
2	zolmitriptan.mp.	577
3	succinate.mp. or Succinic Acid/	32032
4	naratriptan.mp.	314
5	rizatriptan.mp.	467
6	almotriptan.mp.	255
7	frovatriptan.mp.	186
8	eletriptan.mp.	266
9	abobotulinumtoxinA.mp.	275
10	rimabotulinumtoxinB.mp.	576
11	incobotulinumtoxinA.mp.	274
12	onabotulinumtoxinA.mp.	592
13	topiramate.mp. or Topiramate/	4105
14	propranolol.mp. or Propranolol/	43276
15	butalbital.mp.	147
16	dihydroergotamine.mp. or Dihydroergotamine/	1839
17	ergotamine.mp. or Ergotamine/	2876
18	migraine.mp. or Migraine Disorders/	32782
19	limit 18 to (english language and humans)	26160
20	limit 19 to yr="2018 -Current"	749
21	limit 20 to (clinical trial, phase iii or guideline or meta analysis or practice guideline or "systematic review")	46

Topiramate

Goal(s):

- Approve topiramate only for funded diagnoses which are supported by the medical literature (e.g. epilepsy and migraine prophylaxis).

Length of Authorization:

- 90 days to lifetime

Requires PA:

- Non-preferred topiramate products

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Does the patient have diagnosis of epilepsy?	**Yes:** Approve for lifetime (until 12-31-2036)	**No:** Go to #3
3. Does the patient have a diagnosis of migraine?	**Yes:** Approve for 90 days with subsequent approvals dependent on documented positive response for lifetime*	**No:** Go to #4
4. Does the patient have a diagnosis of bipolar affective disorder or schizoaffective disorder?	**Yes:** Go to #5	**No:** Go to #6

Approval Criteria		
5. Has the patient tried or are they contraindicated to at least two of the following drugs? • Lithium • Valproate and derivatives • Lamotrigine • Carbamazepine • Atypical antipsychotic Document drugs tried or contraindications.	**Yes:** Approve for 90 days with subsequent approvals dependent on documented positive response for lifetime approval.*	**No:** Pass to RPh; Deny; medical appropriateness. Recommend trial of 2 covered alternatives.
6. Is the patient using the medication for weight loss? (Obesity ICD10 E669; E6601)?	**Yes:** Pass to RPh. Deny; not funded by the OHP	**No:** Pass to RPh. Go to #7
7. All other indications need to be evaluated for appropriateness: • Neuropathic pain • Post-Traumatic Stress Disorder (PTSD) • Substance abuse	Use is off-label: Deny; medical appropriateness. Other treatments should be tried as appropriate. Use is unfunded: Deny; not funded by the OHP. If clinically warranted: Deny; medical appropriateness. Use clinical judgment to approve for 1 month to allow time for appeal. MESSAGE: "Although the request has been denied for long-term use because it is considered medically inappropriate, it has also been APPROVED for one month to allow time for appeal."	

P&T Review: *5/19; 1/19 (DM); 7/18; 3/18; 3/17; 7/16; 3/15; 2/12; 9/07; 11/07*
Implementation: *4/18/15; 5/12, 1/12*

Botulinum Toxins

Goal(s):
- Approve botulinum toxins for funded OHP conditions supported by evidence of benefit.
- Require positive response to therapy for use in chronic migraine headaches or overactive bladder.

Length of Authorization:
- From 90 days to 12 months

Requires PA:

- Use of botulinum toxins (billed as a physician administered or pharmacy claim) without associated dystonia or neurological disease diagnosis in last 12 months.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. Is this a request for renewal of a previously approved prior authorization for management of migraine headache or detrusor over-activity (e.g., overactive bladder)?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #2
2. What diagnosis is being treated?	Record ICD10 code	
3. Is botulinum toxin treatment for any of the following? a. Upper or lower limb spasticity (G24.02, G24.1, G35, G36.0, I69.03- I69.06 and categories G71, and G80-G83); b. Strabismus due to a neurological disorder (H50.89); c. Blepharospasm (G24.5); d. Spasmodic torticollis (G24.3); e. Torsion dystonia (G24.9); or f. Achalasia (K22.0).	**Yes:** Approve for up to 12 months	**No:** Go to #4
4. Is botulinum toxin treatment for chronic migraine, with ≥15 headache days per month, of which ≥8 days are with migraine?	**Yes:** Go to #5	**No:** Go to #8
5. Is the botulinum toxin administered by, or in consultation with, a neurologist or headache specialist?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
6. Has the patient had an inadequate response, or has contraindications, to at least 3 pharmacological prophylaxis therapies? • Beta-blockers • Tricyclic antidepressants • Anticonvulsants	**Yes:** Go to #7 Baseline headaches/month: _____.	**No:** Pass to RPh. Deny; medical appropriateness. Recommend trial of preferred alternatives at www.orpdl.org/drugs/
7. Do chart notes indicate headaches are due to medication overuse?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Approve no more than 2 injections given ≥3 months apart. Additional treatment requires documented positive response to therapy from baseline (see Renewal Criteria).
8. Is botulinum toxin treatment for idiopathic or neurogenic detrusor over-activity (ICD10-CM N32.81)?	**Yes:** Go to #9	**No:** Pass to RPh. Go to #10
9. Has the patient had an inadequate response to, or is intolerant of, ≥2 incontinence anti-muscarinic drugs (e.g., fesoterodine, oxybutynin, solifenacin, darifenacin, tolterodine, or trospium)?	**Yes:** • Baseline urine frequency/day: _____. • Baseline urine incontinence episodes/day: _____. Approve for up to 90 days. Additional treatment requires documented positive response to therapy from baseline (see Renewal Criteria).	**No:** Pass to RPh. Deny; medical appropriateness.

10. RPh only: Medical literature with evidence for use in funded conditions must be submitted and determined to be appropriate for use before approval is granted.

Deny for the following conditions; not funded by the OHP
Axillary hyperhidrosis and palmar hyperhidrosis (ICD-10 L74.52, R61) Neurologic conditions with none or minimally effective treatment or treatment not necessary (G244; G2589; G2581; G2589; G259); Facial nerve disorders (G510-G519); Spastic dysphonia (J387); Anal fissure (K602); Disorders of sweat glands (e.g., focal hyperhidrosis) (L301; L740-L759; R61); Other disorders of cervical region (M436; M4802; M530; M531; M5382; M5402; M5412; M542; M6788); Acute and chronic disorders of the spine without neurologic impairment (M546; M545; M4327; M4328; M532X7; M532X8; M533; M438X9; M539; M5408; M545; M5430; M5414-M5417; M5489; M549); Disorders of soft tissue (M5410; M609; M790-M792; M797); Headaches (G44209; G44009; G44019; G44029; G44039; G44049; G44059; G44099; G44209; G44219; G44221; G44229; G44309; G44319; G44329; G4441; G4451-G4453; G4459; G4481-G4489; G441; R51); Gastroparesis (K3184) Lateral epicondylitis (tennis elbow)) (M7710-M7712)
Deny for medical appropriateness because evidence of benefit is insufficient

Dysphagia (R130; R1310-R1319);
Other extrapyramidal disease and abnormal movement disorders (G10; G230-GG238; G2401; G244; G250-G26);
Other disorders of binocular eye movements (e.g., esotropia, exotropia, mechanical strabismus, etc.) (H4900-H518);
Tics (F950-F952; F959);
Laryngeal spasm (J385);
Spinal stenosis in cervical region or brachial neuritis or radiculitis NOS (M4802; M5412-M5413);
Spasm of muscle in absence of neurological diagnoses (M6240-M62838);
Contracture of tendon (sheath) in absence of neurological diagnoses (M6240; M62838);
Amyotrophic sclerosis (G1221);
Clinically significant spinal deformity or disorders of spine with neurological impairment (M4800; M4804; M4806; M4808; M5414-M5417);
Essential tremor (G25.0)
Hemifacial spasm (G513)
Occupational dystonias (e.g., “Writer’s cramp”) (G248, G249)
Hyperplasia of the prostate (N400-403; N4283)
Conditions of the back and spine for the treatment of conditions on lines 346 and 527, including cervical, thoracic, lumbar and sacral conditions. See Guideline Note 37.

Renewal Criteria		
1. Is this a request for renewal of a previously approved prior authorization for management of migraine headache?	**Yes:** Go to #2	**No:** Go to #3
2. Is there documentation of a reduction of ≥7 headache days per month compared to baseline headache frequency?	**Yes:** Approve no more than 2 injections given ≥3 months apart. Baseline:____ headaches/month Current:____ headaches/month	**No:** Pass to RPh. Deny; medical appropriateness
3. Is this a request for renewal of a previously approved prior authorization for management of idiopathic or neurogenic detrusor over-activity?	**Yes:** Go to #4	**No:** Go to Approval Criteria
4. Is there a reduction of urinary frequency of ≥8 episodes per day or urinary incontinence of ≥2 episodes per day compared to baseline frequency?	**Yes:** Approve for up to 12 months • Baseline:____ urine frequency/day • Current:____ urine frequency/day -or- • Baseline:____ urine incontinence episodes/day • Current:____ urine incontinence episodes/day	**No:** Pass to RPh. Deny; medical appropriateness

P&T / DUR Review: *5/19 (KS); 9/18; 5/18; 11/15; 9/14; 7/14*
Implementation: *11/1/2018; 7/1/18; 10/13/16; 1/1/16*

Antimigraine - Triptans

Goal(s):

- Decrease potential for medication overuse headache through quantity limits and therapeutic duplication denials.
- Promote PDL options.

Length of Authorization:

- Up to 6 months

Requires PA:

- Non-preferred drugs

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Check the Reason for PA:

- Non-Preferred drugs will deny on initiation
- Preferred drugs will deny only when maximum dose exceeded
- Both will deny for concurrent therapy (concurrent triptans by different routes is allowed)

Quantity Limits per Labeling.

Generic	Brand	Max Daily Dose	Dosage Form	Quantity Limit Per Month
Almotriptan	Axert	25 mg	6.25 mg tab 12.5 mg tab	12 tabs
Eletriptan	Relpax	80 mg	20 mg tab 40 mg tab (blister pack 6, 12)	6 tabs
Frovatriptan	Frova	7.5 mg	2.5 mg tab (blister pack 9)	9 tabs
Naratriptan	Amerge	5 mg	1 mg tab 2.5 mg tab (blister pack 9)	9 tabs
Rizatriptan	Maxalt Maxalt MLT	30 mg	5 mg tab 10 mg tab (blister pack 6, 12)	12 tabs

Generic	Brand	Max Daily Dose	Dosage Form	Quantity Limit Per Month
Sumatriptan tablets	Imitrex & generics	200 mg	25 mg tab, 50 mg tab, 100 mg tab (blister pack 9)	9 tablets
Sumatriptan nasal spray	Imitrex & generics	40 mg	5 mg, 10 mg (box of 6)	18 spray units
Sumatriptan nasal powder	Onzetra Xsail	44 mg	22 mg (11 mg in each nostril)	6 nosepieces
Sumatriptan injectable	Imitrex & generics	12 mg	6 mg/0.5 mL	6 vials
Sumatriptan injectable	Sumavel	12 mg	6 mg/0.5 mL units (package of 6)	6 jet injectors
Sumatriptan injectable	Zembrace Symtouch	12 mg	3 mg/0.5 mL (package of 4)	12 auto-injectors
Sumatriptan /naproxen	Treximet	170/1000 mg (2 tablets)	85/500 mg tab (box of 9)	9 tablets
Zolmitriptan	Zomig Zomig ZMT	10 mg	2.5 mg tab (blister pack, 6)	6 tabs
Zolmitriptan nasal spray	Zomig NS	10 mg	5 mg (box of 6)	3 packages (18 spray units)

Abbreviations: d = days; MR = may repeat; NS = nasal spray; PO = orally

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Does the patient have a diagnosis of migraine headaches?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is requested drug a preferred product?	**Yes:** Go to #5	**No:** Go to #4

Approval Criteria		
4. Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require PA within recommended dose limits. • Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee.	**Yes:** Inform prescriber of covered alternatives in class and dose limits.	**No:** Go to #5
5. Is request for a higher dose than listed in quantity limit chart?	**Yes:** Pass to RPh. Deny; medical appropriateness. • May recommend use of migraine prophylactic therapy and reinforce that doses above those recommended by the manufacturer increase the incidence of medication overuse headache. • One lifetime 90-day taper may be approved at pharmacist's discretion. • Document.	**No:** Trouble-shoot claim payment (e.g., days' supply?). Go to #6.
6. Is the request for two different oral triptans concurrently?	**Yes:** Go to #7	**No:** Approve for 6 months
7. Is this a switch in Triptan therapy due to intolerance, allergy or ineffectiveness?	**Yes:** Document reason for switch and override for concurrent use for 30 days.	**No:** Pass to RPh. Deny; medical appropriateness.

P&T Review: *5/19 (KS); 3/16; 3/10; 9/09; 11/03; 5/03*
Implementation: *5/1/16, 3/23/10; 1/1/10; 7/1/06; 5/31/05; 6/30/04*