UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Triptans

Program	Prior Authorization
Medication	Triptans
Markets in Scope	California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2008
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	3/2021

1. Background:

FDA Approved Indications:

a. Amerge (naratriptan), Frova (frovatriptan), Imitrex tablet/Imitrex nasal spray (sumatriptan), Relpax (eletriptan), Zomig tablet (zolmitriptan), Zomig-ZMT (zolmitriptan orally-disintegrating tablet), Zembrace SymTouch (sumatriptan injection), Onzetra Xsail (sumatriptan nasal powder), Tosymra (sumatriptan nasal spray):

- Migraine Headaches: Indicated for the acute treatment of migraine with or without aura in adults. Not intended for the prophylactic therapy of migraine attacks or for the treatment of cluster headache.

b. Imitrex injection (sumatriptan):

- Migraine Headaches: Indicated for the acute treatment of migraine with or without aura in adults. Not intended for the prophylactic therapy of migraine headache attacks.
- Cluster Headaches: Indicated for the acute treatment of cluster headache in adults. Not intended for the prophylactic therapy of cluster headache attacks.

c. almotriptan:

- Migraine Headaches for adults: Approved for the acute treatment of migraine attacks in adults with a history of migraine with or without aura.
- Migraine Headaches for adolescents: Approved for the acute treatment of migraine headache pain in adolescents age 12 to 17 years with a history of migraine with or without aura, and who have migraine attacks usually lasting 4 hours or more.

d. Maxalt (rizatriptan), Maxalt-MLT (rizatriptan orally-disintegrating tablet):

- Migraine headaches: Indicated for the acute treatment of migraine with or

without aura in adults and in pediatric patients 6 to 17 years old. Not intended for the prophylactic therapy of migraine or for the treatment of cluster headache.

e. Treximet (sumatriptan/naproxen), Zomig Nasal Spray (zolmitriptan)

- Migraine Headaches: Indicated for the acute treatment of migraine attacks with or without aura in adults and pediatric patients 12 years of age and older. Not intended for the prophylactic therapy of migraine attacks or for the treatment of cluster headache.

2. Coverage Criteria:

A. Naratriptan (preferred with Step Therapy)

1. Diagnosis of migraine headaches with or without aura

-AND-

2. History of failure to sumatriptan (generic Imitrex) tablets at a minimum dose of 50mg, or contraindication or intolerance to sumatriptan (generic Imitrex) tablets.

Authorization will be issued for 12 months.

B. Non-Preferred Products

1. Diagnosis of migraine headaches with or without aura

-AND-

2. Patient has a history of failure, contraindication, or intolerance to all of the following (document drugs, duration, and date of trials):

- naratriptan
- rizatriptan
- sumatriptan tablets, nasal spray, 4mg injection, or 6mg injection

Authorization will be issued for 12 months.

C. Requests Above the Quantity Limit –See Section 3 for Quantity Limits Imitrex injection (sumatriptan)- Migraine Headaches (see section D for cluster headaches)

NOTE: This criteria applies to requests above the quantity limit only. Non-preferred products are addressed in Section B.

1. Diagnosis of migraine headaches with or without aura

-AND-

2. Prescribed by or in consultation with one of the following:
   - Neurologist
   - Pain management specialist

-AND-

3. Currently receiving prophylactic therapy with at least **one** of the following:
   - Amitriptyline (Elavil)
   - One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol ***NOTE*** Nadolol and timolol are non-preferred and should not be included in denial to provider
   - Divalproex sodium (Depakote/Depakote ER)
   - OnabotulinumtoxinA (Botox) ***NOTE*** This is a medical benefit, should not be included in denial to provider
   - Topiramate (Topamax)
   - Venlafaxine (Effexor/Effexor XR)
   - Calcitonin gene-related peptide (CGRP) receptor antagonists [eg, Aimovig (erenumab), Emgality (galcanezumab)]

-AND-

4. **One** of the following:

   a. Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

   -OR-

   b. Higher dose or quantity is supported by one of the following compendia:
      - American Hospital Formulary Service Drug Information
      - Thomson Micromedex DrugDex
      - Clinical Pharmacology
      - United States Pharmacopoeia-National Formulary (USP-NF)

   -OR-

   c. Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA for the diagnosis indicated.

-AND-

5. Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Authorization will be issued for 12 months.

D. <u>Requests Above the Quantity Limit –See Section 3 for Quantity Limits</u> Imitrex injection (sumatriptan)- Cluster Headaches (see section C for migraine headaches)

NOTE: This criteria applies to requests above the quantity limit only. Non-preferred products are addressed in Section B.

1. Diagnosis of cluster headaches

-AND-

2. Prescribed by or in consultation with one of the following:
   - Neurologist
   - Pain management specialist

-AND-

3. Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.

-AND-

4. **<u>One</u>** of the following:

   a. Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

   -OR-

   b. Higher dose or quantity is supported by one of the following compendia:
      - American Hospital Formulary Service Drug Information
      - Thomson Micromedex DrugDex
      - Clinical Pharmacology
      - United States Pharmacopoeia-National Formulary (USP-NF)

-OR-

c. Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA for the diagnosis indicated.

-AND-

5. Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Authorization will be issued for 12 months.

E. Requests Above the Quantity Limit –See Section 3 for Quantity Limits Brand and generic Amerge (naratriptan), Generic almotriptan, Brand and generic Frova (frovatriptan), Brand and generic Imitrex tablets/Imitrex nasal spray (sumatriptan), Brand and generic Maxalt/Maxalt MLT (rizatriptan), Onzetra Xsail (sumatriptan), Brand and generic Relpax (eletriptan), Tosymra (sumatriptan nasal spray), Brand and generic Treximet (sumatriptan/naproxen), Zembrace SymTouch (sumatriptan), Brand and generic Zomig/Zomig ZMT (zolmitriptan), Zomig (zolmitriptan) nasal spray

NOTE: This criteria applies to requests above the quantity limit only. Non-preferred products are addressed in Section B.

1. Diagnosis of migraine headaches with or without aura

-AND-

2. Prescribed by or in consultation with one of the following:
   - Neurologist
   - Pain management specialist

-AND-

3. Currently receiving prophylactic therapy with at least **one** of the following:

   - Amitriptyline (Elavil)
   - One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol ***NOTE*** Nadolol and timolol are non-preferred and should not be included in denial to provider
   - Divalproex sodium (Depakote/Depakote ER)
   - OnabotulinumtoxinA (Botox) ***NOTE*** This is a medical benefit, should not be included in denial to provider

- Topiramate (Topamax)
- Venlafaxine (Effexor/Effexor XR)
- Calcitonin gene-related peptide (CGRP) receptor antagonists [eg, Aimovig (erenumab), Emgality (galcanezumab)]

-AND-

4. **One** of the following:

a. Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

-OR-

b. Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Thomson Micromedex DrugDex
- Clinical Pharmacology
- United States Pharmacopoeia-National Formulary (USP-NF)

-OR-

c. Physician provides evidence from published biomedical literature to support safety and additional efficacy at doses/quantities greater than those approved by the FDA for the diagnosis indicated.

-AND-

5. Physician acknowledges that the potential benefit outweighs the risk associated with the higher dose or quantity

Authorization will be issued for 12 months.

3. Quantity Limits: Brand and generic Amerge (naratriptan), Generic almotriptan, Brand and generic Frova (frovatriptan), Brand and generic Imitrex tablets/Imitrex nasal spray/Imitrex injection (sumatriptan), Brand and generic Maxalt/Maxalt MLT (rizatriptan), Onzetra Xsail (sumatriptan), Brand and generic Relpax (eletriptan), Tosymra (sumatriptan nasal spray), Brand and generic Treximet (sumatriptan/naproxen), Zembrace SymTouch (sumatriptan), Brand and generic Zomig/Zomig ZMT (zolmitriptan), Zomig (zolmitriptan) nasal spray

Drug Name	Strength	Quantity Limit
Brand Amerge generic naratriptan	1mg, 2.5mg	9 tabs/month
Brand Frova Generic frovatriptan	2.5mg	9 tabs/month
Brand Imitrex tablets Generic sumatriptan tablets	25mg, 50mg, 100mg	9 tabs/month
Brand Maxalt Generic rizatriptan	5mg, 10mg	9 tabs/month
Brand Maxalt MLT Generic rizatriptan ODT	5mg, 10mg	9 tabs/month
Generic almotriptan	6.25mg, 12.5mg	6 tabs/month
Relpax Generic eletriptan	20mg, 40mg	6 tabs/month
Brand Zomig Generic zolmitriptan	2.5mg, 5mg	6 tabs/month
Brand Zomig ZMT Generic zolmitriptan ODT	2.5mg, 5mg	6 tabs/month
Brand Imitrex nasal spray Generic sumatriptan nasal spray	5mg, 20mg	6 spray devices/month
Zomig nasal spray	2.5mg, 5mg	6 spray devices/month
Treximet Generic sumatriptan/naproxen	85mg/500 mg, 10mg/60mg	9 tabs/month
Onzetra Xsail	11mg	1 box (8 units)/month
Zembrace SymTouch	3mg/0.5mL	2 boxes (8 units)/month
Brand Imitrex Generic Sumatriptan Autoinjector/Cartridge Refills	4mg/0.5mL 6mg/0.5mL	8 autoinjectors or cartridge refills/month (4 boxes/month)
Brand Imitrex Generic Sumatriptan Vials	6mg/0.5mL	10 vials/month (2 boxes/month)

Generic Sumatriptan Pre-filled Syringe	6mg/0.5mL	8 prefilled syringes (4 boxes/month)
Tosymra nasal spray	10mg	6 units per month

4. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

5. References:

1. Almotriptan [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; May 2017.
2. Amerge [package insert]. Research Triangle Park, NC: GlaxoSmithKline; October 2020.
3. Frova [package insert]. Malvern, PA: Endo Pharmaceuticals, Inc.; August 2018.
4. Imitrex Tablets [package insert]. Research Triangle Park: GlaxoSmithKline; September 2020.
5. Imitrex Nasal Spray [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2017
6. Imitrex Injection [package insert]. Research Triangle Park, NC: GlaxoSmithKline; September 2020.
7. Maxalt/Maxalt MLT [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., Inc; September 2020.
8. Onzetra Xsail [package insert]. Morristown, NJ: Currax Pharmaceuticals LLC; December 2019.
9. Relpax [package insert. New York, NY: Pfizer, Inc.; March 2020.
10. Treximet [package insert]. Morristown, NJ: Currax Pharmaceuticals LLC; November 2020.
11. Zembrace SymTouch [package insert]. Princeton, NJ: Promius Pharma, LLC; June 2019.
12. Zomig/Zomig ZMT [package insert]. Bridgewater NJ: Amneal Pharmaceuticals LLC; May 2019.
13. Zomig Nasal Spray [package insert]. Bridgewater NJ: Amneal Pharmaceuticals LLC; May 2019.
14. Tosymra [package insert]. Princeton, NJ: Promius Pharma, LLC; January 2019.
15. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2012 Apr 24;78(17):1337-45.
16. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May 10; 86(19):1818-26.

17. The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache: The Journal of Head and Face Pain. 2019;59: 1-18.

Program	Prior Authorization- Triptans
Change Control	
Date	Change
6/2008	New Policy. (migraine QL)
10/2008	Annual Review(migraine QL)
9/2009	Policy reformatted. (triptans ST)
4/2010	Criteria were taken from a previously approved Unison policy, RX06 Migraine, Acute Treatment. Policy was reformatted. (migraine QL)
9/2010	Frova removed from triptan step therapy criteria. Amerge (naratriptan) added to triptan step therapy criteria. (triptans ST)
6/2011	Annual Review(triptans ST)
12/2011	Annual Review(migraine QL)
6/2012	Annual Review. Updated references. (triptans ST)
12/2012	Annual Review(migraine QL)
6/2013	Combined triptans ST guideline and migraine QL guideline into this single guideline addressing both. Updated QLs for the QL policy. Added diagnosis requirement for triptans ST when automated ST not met. Migraine QL: Complete reorganization of guideline. A full clinical re-review was completed to accomplish this.
9/2013	Updated the prophylaxis therapy list to remove calcium channel blockers and to add angiotensin converting enzyme (ACE) inhibitor [eg, Zestril (lisinipril)], angiotensin receptor blockers [(eg, Atacand (candesartan)] and alpha agonists (eg, clonidine, guanfacine) per the 2012 American Headache Society (AHS)/American Academy of Neurology (AAN) updated guideline
4/2016	Updated policy template. Updated quantity limits.
6/2016	Added Sumachip (sumatriptan and capsaicin-menthol)
7/2016	Updated Section B header and added note under header. Added Section C (non-preferred products) to policy.

8/2016	Added Zembrace SymTouch and Onzetra Xsail to policy
11/2016	Added Sumavel DosePro to policy
3/2017	Added quantity limit to Brand Imitrex (generic sumatriptan) injection.
6/2018	Changed Treximet quantity from 6 to 9 to align with coding.
5/2019	Added CGRP's to the list of prophylactic options for patients requesting above the quantity limit. Language cleanup throughout. Removed Sumachip since it's no longer on the market. Updated references.
8/2019	Removed Sumavel DosePro as it is no longer on the market. Added cluster headaches as an approvable condition for Imitirex injection.
12/2020	Added Tosymra, removed brand Axert. Updated naratriptan ST language to align with coding. Updated Zembrace and sumatriptan injection quantity limits. Language updates in background and criteria with no changes to clinical intent. Updated references.