STEP THERAPY POLICY

POLICY: Migraine Medication Step Therapy Policy

Injectable Triptans

- Alsuma[™] (sumatriptan injection Pfizer, generic)
- Imitrex® (sumatriptan injection GlaxoSmithKline, generic)
- Sumavel® DosePro® (sumatriptan injection Zogenix [obsolete date 02/01/2019])
- Zembrace[™] SymTouch[™] (sumatriptan injection Dr. Reddy's Labs)

Oral Triptans

- Amerge[®] (naratriptan tablets GlaxoSmithKline, generic)
- Axert[®] (almotriptan tablets Ortho-McNeil, generic)
- Frova[®] (frovatriptan tablets Endo Pharmaceuticals, generic)
- Imitrex® (sumatriptan tablets GlaxoSmithKline, generic)
- Maxalt® (rizatriptan tablets Merck, generic)
- Maxalt MLT® (rizatriptan orally disintegrating tablets Merck, generic)
- Relpax[®] (eletriptan tablets Pfizer, generic)
- Treximet® (sumatriptan and naproxen sodium tablets Pernix Therapeutics, generic)
- Zomig[®] (zolmitriptan tablets AstraZeneca, generic)
- Zomig-ZMT® (zolmitriptan orally disintegrating tablets AstraZeneca, generic)

Nasal Medications

- Imitrex[®] (sumatriptan nasal spray GlaxoSmithKline, generic)
- Migranal® (dihydroergotamine mesylate nasal spray Valeant, authorized generic)
- Onzetra[™] Xsail[™] (sumatriptan nasal powder Currax Pharmaceuticals)
- Tosymra[™] (sumatriptan nasal spray Promius)
- Trudhesa[™] (dihydroergotamine mesylate nasal spray Impel NeuroPharma)
- Zomig® (zolmitriptan nasal spray AstraZeneca, generic)

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OVERVIEW

All of the triptan medications, including Treximet (the combination sumatriptan-naproxen sodium agent), are indicated for the **treatment of migraine headache** with or without aura in adults and are not intended to be used as prophylactic migraine therapy or to manage hemiplegic or basilar migraine. Only sumatriptan injection is approved for the treatment of cluster headache. Safety and efficacy have not been established for treatment of cluster headache for the oral dosage forms of all triptans. Some of the triptan medications are also indicated for use in children and/or adolescents. Almotriptan is approved for the treatment of migraine headache pain in adolescent patients 12 to 17 years of age with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated). Rizatriptan is approved for the acute treatment of migraine with or without aura in patients \geq 6 years of age. Treximet and zolmitriptan nasal spray are approved for the acute treatment of migraine with or without aura in patients \geq 12 years of age. All 11

Rizatriptan orally disintegrating tablets and zolmitriptan orally disintegrating tablets offer the convenience of not requiring liquids for oral administration.^{4,5} Treximet offers the convenience of two agents (triptan and non-steroidal anti-inflammatory drug [NSAID]) with pharmacologically different mechanisms of action in one tablet.⁹

Migranal and Trudhesa, ergot alkaloids, are nasal sprays indicated for the acute treatment of migraine headaches in adults with or without aura. 17,18 Migranal and Trudhesa are not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

- Step 1: generic almotriptan tablets, generic eletriptan tablets, generic frovatriptan tablets, generic naratriptan tablets, generic rizatriptan tablets, generic rizatriptan orally disintegrating tablets, generic sumatriptan tablets, generic sumatriptan nasal spray, generic sumatriptan injection, generic zolmitriptan orally disintegrating tablets, generic zolmitriptan tablets
- Step 2: Alsuma Injection, Amerge tablets, Axert tablets, Frova tablets, Imitrex tablets, Imitrex Nasal Spray, Imitrex Injection, Maxalt tablets, Maxalt MLT, Migranal (brand and generic), Onzetra Xsail, Relpax, Sumavel Dosepro, Tosymra, Treximet tablets (brand and generic), Trudhesa, Zembrace Symtouch, Zomig tablets, Zomig-ZMT, Zomig nasal spray, zolmitriptan nasal spray

CRITERIA

- 1. If the patient has tried one Step 1 Product, approve a Step 2 Product. Note: Zomig Nasal Spray with DAW 9 (indicating that substitution is allowed by the prescriber but the Plan requests brand) will also count as a Step 1 Product.
- 2. No other exceptions are recommended.

REFERENCES

- 1. Frova[®] tablets [prescribing information]. Malvern, PA; Endo Pharmaceuticals; August 2018.
- Amerge[®] tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; November 2016.
- 3. Maxalt® tablets and Maxalt-MLT® orally disintegrating tablets [prescribing information]. Whitehouse Station, NJ: Merck; October 2019.
- 4. Zomig[®] tablets and Zomig-ZMT[®] orally disintegrating tablets [prescribing information]. Wilmington, DE: AstraZeneca; December 2018.
- 5. Imitrex® tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
- Axert® tablets [prescribing information]. Raritan, NJ: Ortho-McNeil; May 2017.
- Relpax® tablets [prescribing information]. New York, NY: Pfizer; March 2020.
- Treximet® tablets [prescribing information]. Morristown, NJ: Pernix Therapeutics; July 2019.
- 9. Imitrex® nasal spray [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
- 10. Imitrex® injection [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; July 2018.
- 11. Zomig® nasal spray [prescribing information]. Wilmington, DE: AstraZeneca; December 2018.
- 12. Sumavel® DosePro® [prescribing information]. Malvern, PA: Endo Pharmaceuticals; January 2020.
- Alsuma[™] [prescribing information]. New York, NY: Pfizer; April 2014.
 Onzetra[™] Xsail[™] nasal powder [prescribing information]. Morristown, NJ: Currax[™] Pharmaceuticals; December 2019.
- 15. Zembrace[™] SymTouch[™] injection [prescribing information]. Princeton, NJ: Promius Pharma; June 2019.
- 16. Tosymra[™] nasal spray [prescribing information]. Princeton, NJ: Promius Pharma; January 2019.

Migraine Medication Step Therapy Policy Page 3

- 17. Migranal[®] nasal spray [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; August 2019.
 18. Trudhesa[™] nasal spray [prescribing information]. Seattle, WA: Impel NeuroPharma; September 2021.