SmartPA Criteria Proposal

Drug/Drug Class:	Anti-Migraine, Serotonin (5-HT1) Receptor Agonists PDL Edit
First Implementation Date:	June 15, 2005
Proposed Date:	December 16, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Migraine headache is a chronic, debilitating condition that tends to afflict young, productive, otherwise healthy people. The triptans are agents indicated to abort acute migraine attacks and cluster headache (sumatriptan injection only). These agents offer selective pharmacology, established efficacy, a moderate side effect profile, and a well-established safety record. The disadvantages of these agents are their restrictions for use in the presence of cardiovascular disease and cost variability.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Rizatriptan • Sumatriptan	• Almotriptan • Amerge® • Eletriptan • Frova® • Frovatriptan • Imitrex® • Maxalt® • Maxalt-MLT® • Naratriptan • Onzetra® Xsail® • Relpax® • Sumatriptan/Naproxen • Tosymra® • Treximet® • Zembrace® SymTouch® • Zolmitriptan • Zomig® Nasal Spray/Tabs • Zomig- ZMT®

Type of Criteria:	☐ **Increased risk of ADE**	☒ **Preferred Drug List**
	☐ **Appropriate Indications**	☐ **Clinical Edit**
Data Sources:	☐ **Only Administrative Databases**	☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Anti-Migraine, Serotonin (5-HT1) Receptor Agonists
- Age range: All appropriate MO HealthNet participants aged 6 years and older

Approval Criteria

- ~~**Documented diagnosis of cluster headaches AND claim is for sumatriptan injection (excluding Zembrace) OR**~~
- ~~**Documented diagnosis of migraine AND**~~
- Participants aged ≥ 6 years and < 12 years: rizatriptan only **OR**
- Participants aged ≥ 12 years and < 18 years:
  - Claim is for rizatriptan **OR**
  - Claim is for almotriptan, sumatriptan/naproxen, or zolmitriptan nasal spray **AND**
    - Failure to achieve desired therapeutic outcomes with therapeutic trial of rizatriptan in the past 12 months **OR**
    - Documented ADE/ADR to rizatriptan **OR**
- Participants aged ≥ 18 years:
  - Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
    - Documented trial period for preferred agents **OR**
    - Documented ADE/ADR to preferred agents **OR**
  - For long acting 5-HT1 receptor agonists:
    - Failure to achieve desired therapeutic outcomes with therapeutic trial of naratriptan in the past 6 months **AND**
    - Failure to achieve desired therapeutic outcomes with therapeutic trial on 1 or more preferred agents in the past 6 months

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Requests for triptan therapy will be denied in the absence of approval criteria and under the following conditions:
  - Ischemic heart disease
  - Peripheral vascular syndromes
  - Cerebrovascular disease
  - ~~**Uncontrolled hypertension**~~
  - Hemiplegic or basilar migraine
  - Concurrent ergot therapy
  - Concurrent MAOI therapy
- Claim exceeds maximum dosing limitations for the following:

Drug Description	Generic Equivalent	Max Units Per Month
AMERGE 1 MG TABLET	NARATRIPTAN HCL	9 tabs (1 package)
AMERGE 2.5 MG TABLET	NARATRIPTAN HCL	9 tabs (1 package)
AXERT 12.5 MG TABLET (12 tab/pkg)	ALMOTRIPTAN MALATE	8 tabs
AXERT 6.25 MG TABLET (12 tab/pkg)	ALMOTRIPTAN MALATE	8 tabs
FROVA 2.5 MG TABLET	FROVATRIPTAN SUCC	9 tabs (1 package)

IMITREX 100 MG TABLET	SUMATRIPTAN SUCCINATE	9 tabs (1 package)
IMITREX 20 MG NASAL SPRAY	SUMATRIPTAN	12 units (2 boxes)
IMITREX 25 MG TABLET	SUMATRIPTAN SUCCINATE	9 tabs (1 package)
IMITREX 4 MG/0.5 ML CARTRIDGES	SUMATRIPTAN SUCCINATE	4 mL (8 carts - 4 boxes)
IMITREX 4 MG/0.5 ML PEN INJECT	SUMATRIPTAN SUCCINATE	4 mL (8 pens - 4 boxes)
IMITREX 5 MG NASAL SPRAY	SUMATRIPTAN	12 units (2 boxes)
IMITREX 50 MG TABLET	SUMATRIPTAN SUCCINATE	9 tabs (1 package)
IMITREX 6 MG/0.5 ML CARTRIDGES	SUMATRIPTAN SUCCINATE	4 mL (8 carts - 4 boxes)
IMITREX 6 MG/0.5 ML PEN INJECT	SUMATRIPTAN SUCCINATE	4 mL (8 pens - 4 boxes)
IMITREX 6 MG/0.5 ML VIAL	SUMATRIPTAN SUCCINATE	4 mL (8 vials)
MAXALT 10 MG TABLET (18 tab/pkg)	RIZATRIPTAN BENZOATE	8 tabs
MAXALT 5 MG TABLET (18 tab/pkg)	RIZATRIPTAN BENZOATE	8 tabs
MAXALT MLT 10 MG TABLET (18 tab/pkg)	RIZATRIPTAN BENZOATE	8 tabs
MAXALT MLT 5 MG TABLET (18 tab/pkg)	RIZATRIPTAN BENZOATE	8 tabs
ONZETRA XSAIL 11 MG	SUMATRIPTAN SUCCINATE	16 units (1 box)
RELPAX 20 MG TABLET	ELETRIPTAN HBR	6 tabs (1 package)
RELPAX 40 MG TABLET	ELETRIPTAN HBR	6 tabs (1 package)
SUMATRIPTAN 6 MG/0.5 ML SYRNG	SUMATRIPTAN SUCCINATE	4 mL (8 syr - 4 boxes)
SUMAVEL DOSEPRO 4 MG/0.5 ML	SUMATRIPTAN SUCCINATE	6 mL (12 pens - 2 boxes)
SUMAVEL DOSEPRO 6 MG/0.5 ML	SUMATRIPTAN SUCCINATE	6 mL (12 pens - 2 boxes)
TOSYMRA 10 MG NASAL SPRAY	SUMATRIPTAN	12 units (2 boxes)
TREXIMET 10-60 MG TABLET (9 tab/pkg)	SUMATRIPTAN/NAPROXEN	4 tabs
TREXIMET 85-500 MG TABLET	SUMATRIPTAN/NAPROXEN	9 tabs (1 package)
ZEMBRACE SYMTOUCH 3 MG/0.5 ML	SUMATRIPTAN SUCCINATE	8 mL (16 units - 4 boxes)
ZOMIG 2.5 MG NASAL SPRAY	ZOLMITRIPTAN	12 units (2 boxes)
ZOMIG 2.5 MG TABLET	ZOLMITRIPTAN	6 tabs (1 package)
ZOMIG 5 MG NASAL SPRAY	ZOLMITRIPTAN	12 units (2 boxes)
ZOMIG 5 MG TABLET	ZOLMITRIPTAN	6 tabs (1 package)
ZOMIG ZMT 2.5 MG TABLET	ZOLMITRIPTAN	6 tabs (1 package)
ZOMIG ZMT 5 MG TABLET	ZOLMITRIPTAN	6 tabs (1 package)

- Maximum monthly dose calculated at treating 4 episodes per month, 2 doses per episode: Amerge, Axert, Frova, Imitrex, Maxalt, Migranow, Onzetra Xsail, Sumavel, Tosymra, Treximet 85/500, Zembrace, Zomig Nasal
- Maximum monthly dose calculated at treating 3 episodes per month, 2 doses per episode: Relpax, Zomig tablets
- Maximum monthly dose calculated at treating 2 episodes per month, 2 doses per episode: Treximet 10/60

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

6 months

References

- Evidence-Based Medicine and Fiscal Analysis: “Serotonin Receptor Agonists (Triptans) – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; November 2021.
- Evidence-Based Medicine Analysis: “Serotonin Receptor Agonists (Triptans)”, UMKC-DIC; August 2021.
- USPDI, Micromedex; 2021.
- Drug Facts and Comparisons On-line; 2021.