Clinical Policy: Triptans

Reference Number: CP.CPA.217
Effective Date: 11.16.16
Last Review Date: 11.19
Line of Business: Commercial

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The following are triptans requiring prior authorization and/or quantity limits: naratriptan (Amerge®), almotriptan (Axert®), frovatriptan (Frova®), sumatriptan (Imitrex®, Tosymra™), rizatriptan (Maxalt®/Maxalt-MLT®), eletriptan (Relpax®), sumatriptan/naproxen (Treximet®), zolmitriptan (Zomig®/Zomig® ZMT), Imitrex® injection, Onzetra™ Xsail™, Sumavel™ Dosepro™, and Zembrace™ SymTouch™.

FDA Approved Indication(s)

Triptans are indicated for the acute treatment of migraine attacks with or without aura in:

- Adults (all products)
- Pediatric patients (certain products only):
  - Axert: age 12 to 17 years with a history of migraine attacks usually lasting 4 hours or more (when untreated)
  - Maxalt, Maxalt MLT: age 6 to 17 years old
  - Treximet, Zomig Nasal Spray: age 12 to 17 years

Imitrex injection and Sumavel DosePro are additionally indicated for the treatment of acute treatment of cluster headache in adults.

Limitation(s) of use:

- Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with a specific triptan, reconsider the diagnosis of migraine before that triptan is administered to treat any subsequent attacks.
- Triptans are not indicated for the prevention of migraine attacks.
- In adolescents age 12 to 17 years, efficacy of Axert on migraine-associated symptom (nausea, photophobia, and phonophobia) was not established.
- Axert and Maxalt are not intended for use in the management of hemiplegic or basilar migraine.
- Safety and effectiveness of triptans have not been established for cluster headache.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Amerge, Axert, Frova, Imitrex, Maxalt, Maxalt MLT, Relpax, Tosymra, Treximet, Zomig, Zomig ZMT, Imitrex

injection, Onzetra Xsail, Sumavel Dosepro, and Zembrace are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Migraines – Oral Agents (*see Sections I.B and I.C for non-oral triptans*) (must meet all)**:**

1. Diagnosis of migraine headaches;
2. Request is for an oral agent;
3. Member meets the following age requirements:
   a. For Amerge, Frova, Imitrex, Relpax, Zomig, Zomig-ZMT: Age ≥ 18 years;
   b. For Axert, Treximet: Age ≥ 12 years;
   c. For Maxalt, Maxalt-MLT: Age ≥ 6 years;
4. For non-preferred agents (including Frova, Relpax, Treximet, Zomig), member meets one of the following (a or b):
   a. Failure of at least TWO formulary $5HT_1$-agonist migraine medications (e.g., almotriptan, naratriptan, rizatriptan, or sumatriptan) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. For Treximet requests for members age 12 – 17 years: Failure of almotriptan and rizatriptan, unless contraindicated or clinically significant adverse effects are experienced;
5. For all Treximet requests: Medical justification supports inability to use the individual components (i.e., sumatriptan and naproxen) concurrently (e.g., contraindications to the excipients of all brand and generic products);
6. Requests for monthly quantities greater than the health plan limit but ≤ 2 times the health plan limit, member meets one of the following (a or b):
   a. Failure of TWO prophylactic migraine medications, unless contraindicated or clinically significant adverse effects are experienced *(see Appendix B)*;
   b. Member is being treated by or in consultation with a neurologist or a headache specialist;
7. Requests for monthly quantities > 2 times the health plan limit, member meets both of the following (a and b):
   a. Failure of TWO prophylactic migraine medications, unless contraindicated or clinically significant adverse effects are experienced *(see Appendix B)*;
   b. Member is being treated by or in consultation with a neurologist or a headache specialist;
8. Dose does not exceed the FDA-approved maximum dose *(see Section V)*.

Approval duration: Length of Benefit

B. Migraines – Non-Oral Agents (must meet all)**:**

1. Diagnosis of migraine headaches;
2. Request is for a non-oral agent (i.e., nasal spray or injectable);
3. Member meets the following age requirements:
   a. For Zomig, Imitrex nasal spray: Age ≥ 12 years;
   b. For Imitrex injection, Onzetra Xsail, Sumavel DosePro, Tosymra, Zembrace SymTouch: Age ≥ 18 years;

4. Failure of sumatriptan (Imitrex) nasal spray, unless contraindicated or clinically significant adverse effects are experienced;
5. Member meets one of the following (a or b):
   a. Failure of at least TWO oral generic $5HT_1$-agonist migraine medications (e.g., almotriptan, naratriptan, rizatriptan/rizatriptan ODT, or sumatriptan succinate) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. Member cannot take oral agents due to migraine-associated nausea;
6. For requests for monthly quantities > 2 kits per month (Imitrex injection, Zembrace SymTouch), > 6 nasal spray devices per month (Imitrex, Tosymra, Zomig nasal spray), or > 1 kit per month (Sumavel DosePro, Onzetra Xsail), member meets both of the following (a and b):
   a. Failure of at least TWO prophylactic migraine medications at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced *(see Appendix B for examples)*;
   b. Member is being treated by or in consultation with a neurologist or a headache specialist;
7. Dose does not exceed the following:
   a. Imitrex nasal spray: 40 mg per day;
   b. Tosymra nasal spray: 30 mg per day;
   c. Zomig nasal spray: 10 mg per day;
   d. Imitrex injection, Sumavel DosePro, Zembrace SymTouch: 12 mg per day;
   e. Onzetra Xsail: 44 mg per day (4 capsules per day).

Approval duration:
Imitrex, Tosymra, and Zomig nasal spray – Length of Benefit
All others – 6 months or to the member's renewal period, whichever is longer

C. Cluster Headaches (must meet all)**:**
1. Diagnosis of cluster headaches;
2. Request is for Imitrex nasal spray, Imitrex injection, Sumavel DosePro, or Zomig;
3. Prescribed by or in consultation with a neurologist or headache specialist;
4. Age ≥ 18 years;
5. Dose does not exceed either of the following (a, b, or c):
   a. Imitrex nasal spray: 40 mg per 24 hours;
   b. Imitrex injection or Sumavel DosePro: 12 mg per day;
   c. Zomig: 10 mg per day.

Approval duration:
Nasal spray – Length of Benefit
Injection – 6 months or to the member's renewal period, whichever is longer

D. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the FDA-approved maximum dose *(see Section V)*.

Approval duration:
Oral formulations and nasal spray – Length of Benefit
Injection – 6 months or to the member's renewal period, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months for oral/nasal spray triptans or 6 months for other non-oral triptans (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.CPA.09 or evidence of coverage documents;
B. Management of hemiplegic or basilar migraines;
C. Prophylactic therapy of migraine.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AAN: American Academy of Neurology
FDA: Food and Drug Administration
MAO: monoamine oxidase

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
naratriptan (Amerge®)	One tablet (1 or 2.5 mg) PO at onset; can be repeated in 4 hours	5 mg/day
sumatriptan (Imitrex® nasal spray)	One spray (5 - 20mg) at onset into one nostril; can be repeated in 2 hours	40 mg/day
sumatriptan (Imitrex® tablets)	One tablet (25 -100mg) PO at onset; can be repeated in two hours	200 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
rizatriptan (Maxalt® /Maxalt MLT® tablets)	One tablet (5 or 10 mg) PO at onset of migraine headache; can be repeated in two hours	30 mg/day

Preventive Therapies for Migraine (Adopted by the American Academy of Neurology [AAN])		
Medication	**Dose**	**Level of Evidence****
Anticonvulsants		
divalproex sodium (Depakote®)	500-1,000 mg/day PO	FDA-approved
divalproex sodium ER (Depakote® ER)	500-1,000 mg/day PO	FDA-approved
gabapentin (Neurontin®)	900-2,400 mg/day PO	Group II
topiramate (Topamax®)	100 mg/day PO	FDA-approved
Beta-Blockers		
atenolol (Tenormin®)	100 mg/day PO	Group II
metoprolol (Lopressor®)	200 mg/day PO	Group II
nadolol (Corgard®)	80-240 mg/day PO	Group II
propranolol (Inderal®)	80-240 mg/day PO	Group I
timolol (Blocadren®)	20-30 mg/day PO	Group I
Calcium Channel Blockers		
verapamil (Calan®)	240 mg/day PO	Group II
SSRIs		
fluoxetine (Prozac®)	20 mg QOD - 40 mg/day PO	Group II
Tricyclic Antidepressants		
amitriptyline (Elavil®)	30-150 mg/day PO	Group I
imipramine (Tofranil®)	Not established	Group III
nortriptyline (Pamelor®)	Not established	Group III

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Group I = Medium to high efficacy, good strength of evidence, and mild to moderate side effects; Group II = Lower efficacy than Group I, or limited strength of evidence, and mild to moderate side effects; Group III = Clinically efficacious

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - All triptans:
    - History of coronary artery disease or coronary vasospasm; symptomatic Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders; history of stroke, transient ischemic attack, or hemiplegic or basilar migraine, or peripheral vascular disease; ischemic bowel disease; or uncontrolled hypertension.
    - Recent (within 24 hours) used of another 5-HT1 agonist (e.g., another triptan), or an ergotamine-containing medication.

- Relpax: within at least 72 hours of treatment with the following potent CYP3A4 inhibitors: ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir or nelfinavir.
- Imitrex, Tosymra, Zomig: use concurrently or within 2 weeks of discontinuation of an MAO-A inhibitor or non-selective MAO inhibitor.

- Boxed warning(s):
  - Treximet: risk of serious cardiovascular and gastrointestinal events
  - All other triptans: none reported

Appendix D: General Information

- The triptans should not be used for hemiplegic or basilar migraines due to an increased risk of stroke.
- Imitrex and Zomig are metabolized by monoamine oxidase A (MAO-A), and inhibitors of this enzyme may increase serum concentrations of these triptans.
- AAN guidelines for cluster headaches support the use of Imitrex nasal spray for acute treatment (Level B). Per AAN, intranasal sumatriptan at a dose of 20 mg has been shown to be effective in the acute treatment of cluster headache. Zolmitriptan nasal spray (Level A) 5 mg and 10 mg and zolmitriptan oral (Level B) 5 mg and 10 mg are also recommended by AAN.
- According to AAN guidelines, verapamil, lithium and melatonin may be considered (Level C) for the prevention of cluster headaches.
- The AAN recommends that prophylactic migraine medications should be considered if the patient experiences 2 or more attacks per month that produce aggregate disability of 3 or more days/month.
- The AAN and the National Headache Foundation recommend that prophylactic migraine medications should be considered if one or more of the following are present: greater than 2 migraine headaches per week; migraines cause significant impairment in daily routine even with abortive treatment; contraindication to, adverse effects, overuse or failure of abortive migraine medications, presence of uncommon migraine condition (e.g., basilar migraine); or patient requesting prophylactic therapy.
  - Sumavel is a needle-free injection system, although there is still pain associated with administration.

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Naratriptan (Amerge)	1 or 2.5 mg PO QD May repeat dose in 4 hours	5 mg/24 hours
Sumatriptan (Imitrex) tablet	25 to 100 mg PO QD May repeat dose in 2 hours	200 mg/24 hours
Almotriptan (Axert)	6.25 to 12.5 mg PO QD May repeat dose in 2 hours	25 mg/24 hours
Frovatriptan (Frova)	2.5 mg PO QD May repeat dose in 2 hours	7.5 mg/24 hours
Rizatriptan (Maxalt/Maxalt-MLT)	Adults: 5 or 10 mg PO QD May repeat dose in 2 hours	Adults: 30 mg/24 hours

Drug Name	Dosing Regimen	Maximum Dose
	Pediatrics: < 40 kg: 5 mg PO QD ≥ 40 kg: 10 mg PO QD	Pediatrics: 1 dose/24 hours
Sumatriptan nasal spray (Imitrex)	One spray (5-20 mg) intranasally at onset into one nostril May repeat dose in 2 hours	40 mg/24 hours
Eletriptan (Relpax)	20 or 40 mg PO QD May repeat dose in 2 hours	40 mg/dose 80 mg/24 hours
Zolmitriptan (Zomig and Zomig ZMT)	1.25 or 2.5 mg PO QD May repeat dose in 2 hours	5 mg/dose 10 mg/24 hours
Zomig nasal spray (zolmitriptan)	Adults and Pediatrics 2.5 mg intranasally into one nostril May repeat dose in 2 hours	5 mg/dose 10 mg/24 hours
Sumatriptan/naproxen (Treximet)	Adults 1 tablet (85 mg sumatriptan/500 mg naproxen) PO QD May repeat dose in 2 hours Pediatrics: 12 to 17 years of age 1 tablet (10 mg sumatriptan/60 mg naproxen) PO QD	Adults: 2 tablets/24 hours Pediatrics: 12 to 17 years of age: 1 tablet (85 mg sumatriptan/500 mg naproxen)/24 hours
Sumatriptan succinate injection (Imitrex injection)	Migraines: One injection SC at onset; may repeat after one hour Cluster headaches: One injection SC at onset; may repeat after one hour	2 injections/24 hours
Sumatriptan needle-free delivery system (Sumavel DosePro)	Migraines: 4 mg or 6 mg SC at onset; may repeat after one hour Cluster headaches: 6 mg SC at onset; may repeat after one hour	2 injections/24 hours
Sumatriptan nasal powder (Onzetra Xsail)	Migraines: 22 mg administered by use of one nosepiece (11 mg) in each nostril; may repeat after 2 hours	44 mg/day
Sumatriptan auto-injector (Zembrace SymTouch)	Migraines: 3 mg dose SC at onset; may repeat for 3 additional doses separated by at least 1 hour	12 mg/day
Sumatriptan nasal spray (Tosymra)	Migraines: 10 mg intranasally into one nostril; may repeat after one hour	30 mg/24 hours

VI. Product Availability

Drug	Availability
Naratriptan (Amerge)	Tablet: 1 mg, 2.5 mg (package size 9)
Almotriptan (Axert)	Tablet: 6.25 mg (package size 6), 12.5mg (package size 12)
Frovatriptan (Frova)	Tablet: 2.5 mg (package size 9)
Rizatriptan (Maxalt/ Maxalt MLT)	Tablet: 5 mg, 10 mg (package size 6, 12, 18) MLT tablet: 5 mg, 10 mg (package size 3, 6, 9, 12, 18)
Sumatriptan (Imitrex)	Tablet: 25 mg, 50 mg, 100 mg (package size 9)
Sumatriptan nasal spray (Imitrex Nasal)	Nasal spray device: 5 mg, 20 mg (package size 6)
Eletriptan (Relpax)	Tablet: 20 mg (package size 6), 40 mg (package size 6, 12)
Zolmitriptan (Zomig)	Tablet: 2.5 mg (package size 6), 5 mg (package size 3)
Zolmitriptan nasal spray (Zomig Nasal Spray)	Nasal spray: 2.5 mg, 5 mg (package size 6)
Zolmitriptan orally disintegrating (Zomig ZMT)	Tablet: 2.5 mg (package size 6), 5 mg (package size 3)
Sumatriptan-naproxen (Treximet)	Tablet: 85 mg sumatriptan/500 mg naproxen sodium (package size 9, 12), 10 mg sumatriptan/60 mg naproxen sodium (package size 9)
Sumatriptan succinate solution auto-injector (Imitrex STATdose System)	Each package contains 1 pen with 2 prefilled single dose syringe cartridges: 4 mg/0.5 mL, 6 mg/0.5 mL
Sumatriptan succinate solution cartridge (Imitrex injection cartridge)	2 prefilled syringe cartridges for refill: 4 mg/0.5 ml, 6 mg/0.5 ml
Sumatriptan succinate (Imitrex injection)	Single-dose vials: 6 mg (6 mg/0.5 mL) in cartons of 5 vials
Sumatriptan nasal powder (Onzetra Xsail)	Capsule in disposable nosepiece: 11 mg (kit contains 8 doses)
Sumatriptan needle-free delivery system (Sumavel DosePro)	Prefilled, single-dose units: 4 mg/0.5 mL, 6 mg/0.5mL (package contains six units)
Sumatriptan auto-injector (Zembrace SymTouch)	Prefilled, single-dose auto-injector: 3 mg/0.5 mL (4 auto-injectors per carton)
Sumatriptan nasal spray (Tosymra)	Nasal spray, single-dose: 10 mg (package size 6)

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	06.15.17	11.17
4Q 2018 annual review: no significant changes; combined oral and non-oral triptans policies (retired CP.CPA.260 – Sumatriptan Non-oral Forms); removed Zecuity from the policy as it is no longer commercially available; added product-specific age limits; references reviewed and updated.	07.30.18	11.18
4Q 2019 annual review: Section IA added requirement to clarify request is for an oral formulation; Section IB added Imitrex nasal spray which had a quantity limit, added reference to quantity limit for nasal spray formulations of 6 spray devices per month; cluster headaches: added Zomig which is supported by AAN guidelines; references reviewed and updated.	08.08.19	11.19
Added Tosymra to policy per SDC and prior clinical guidance.	02.19.20	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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