Reference number(s)
903-J, 1-J

Post Limit Prior Authorization
5-HT_1 Agonists
Combinations, All Dosage Forms

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
almotriptan (brand unavailable)	almotriptan	all
Frova	frovatriptan	all
Imitrex	sumatriptan	all
Maxalt	rizatriptan	all
Maxalt-MLT	rizatriptan	all
naratriptan (brand unavailable)	naratriptan	all
Onzetra Xsail	sumatriptan	all
Relpax	eletriptan	all
Symbravo	meloxicam/rizatriptan	all
Tosymra	sumatriptan	all
Treximet	sumatriptan/naproxen	all
Zembrace SymTouch	sumatriptan	all
zolmitriptan (brand unavailable)	zolmitriptan	orally disintegrating tablets (ODT)
Zomig	zolmitriptan	all

Indications

Almotriptan

FDA-approved Indications

Adults: Almotriptan tablets are indicated for the acute treatment of migraine attacks in patients with a history of migraine with or without aura.

Adolescents Age 12 to 17 Years: Almotriptan tablets are indicated for the acute treatment of migraine headache pain in patients with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated).

Limitations of Use

Almotriptan tablets should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with almotriptan tablets, the diagnosis of migraine should be reconsidered before almotriptan tablets are administered to treat any subsequent attacks.

In adolescents age 12 to 17 years, efficacy of almotriptan tablets on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Almotriptan tablets are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine.

Safety and effectiveness of almotriptan tablets have not been established for cluster headache which is present in an older, predominantly male population.

Frova

FDA-approved Indications

Frova is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use

- Use only if a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Frova, reconsider the diagnosis of migraine before Frova is administered to treat any subsequent attacks.
- Frova is not indicated for the prevention of migraine attacks.
- Safety and effectiveness of Frova have not been established for cluster headache.

Imitrex Injection

FDA-approved Indications

Imitrex injection is indicated in adults for (1) the acute treatment of migraine, with or without aura, and (2) the acute treatment of cluster headache.

Limitations of Use

- Use only if a clear diagnosis of migraine or cluster headache has been established. If a patient has no response to the first migraine or cluster headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks.
- Imitrex injection is not indicated for the prevention of migraine or cluster headache attacks.

Imitrex Nasal Spray

FDA-approved Indications

Imitrex Nasal Spray is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use

- Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Imitrex, reconsider the diagnosis of migraine before Imitrex is administered to treat any subsequent attacks.
- Imitrex is not indicated for the prevention of migraine attacks.
- Safety and effectiveness of Imitrex nasal spray and Imitrex tablets have not been established for cluster headache.

Compendial Uses

Acute treatment of cluster headache[19]

Imitrex Tablets

FDA-approved Indications

Imitrex Tablets are indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use

- Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Imitrex, reconsider the diagnosis of migraine before Imitrex is administered to treat any subsequent attacks.
- Imitrex is not indicated for the prevention of migraine attacks.
- Safety and effectiveness of Imitrex nasal spray and Imitrex tablets have not been established for cluster headache.

Maxalt and Maxalt-MLT

FDA-approved Indications

Maxalt and Maxalt-MLT are indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old.

Limitations of Use

- Maxalt should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Maxalt, the diagnosis of migraine should be reconsidered before Maxalt is administered to treat any subsequent attacks.
- Maxalt is not indicated for use in the management of hemiplegic or basilar migraine.
- Maxalt is not indicated for the prevention of migraine attacks.
- Safety and effectiveness of Maxalt have not been established for cluster headache.

Naratriptan

FDA-approved Indications

Naratriptan tablets are indicated for the acute treatment of migraine with or without aura in adults.

Limitations 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 naratriptan tablets reconsider the diagnosis of migraine before naratriptan tablets are administered to treat any subsequent attacks.
- Naratriptan tablets are not indicated for the prevention of migraine attacks.
- Safety and effectiveness of naratriptan tablets have not been established for cluster headaches.

Onzetra Xsail

FDA-approved Indications

Onzetra Xsail is indicated for the acute treatment of migraine with or without aura in adults.

Limitations 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 Onzetra Xsail, reconsider the diagnosis of migraine before treatment of subsequent attacks with Onzetra Xsail.
- Onzetra Xsail is not indicated for the prevention of migraine attacks.
- Safety and effectiveness of Onzetra Xsail have not been established for the treatment of cluster headache.

Compendial Uses

Acute treatment of cluster headache[19]

Relpax

FDA-approved Indications

Relpax is indicated for the acute treatment of migraine attacks with or without aura in adults.

Limitations 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 Relpax, reconsider the diagnosis of migraine before Relpax is administered to treat any subsequent attacks.
- Relpax is not indicated for the prevention of migraine attacks.
- Safety and effectiveness of Relpax have not been established for the treatment of cluster headache.

Symbravo

FDA-approved Indications

Symbravo is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use

- Symbravo should only be used where a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Symbravo, the diagnosis of migraine should be reconsidered before Symbravo is administered to treat any subsequent attacks.
- Symbravo is not indicated for the preventive treatment of migraine attacks.
- Symbravo is not indicated for the treatment of cluster headache.

Tosymra

FDA-approved Indications

Tosymra is indicated for the acute treatment of migraine with or without aura in adults.

Limitations 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 Tosymra, reconsider the diagnosis before Tosymra is administered to treat any subsequent attacks.
- Tosymra is not indicated for the preventive treatment of migraine.
- Tosymra is not indicated for the treatment of cluster headache.

Compendial Uses

Acute treatment of cluster headache[19]

Treximet

FDA-approved Indications

Treximet is indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

Limitations of Use

- Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Treximet, reconsider the diagnosis of migraine before Treximet is administered to treat any subsequent attacks.
- Treximet is not indicated for the prevention of migraine attacks.
- Safety and effectiveness of Treximet have not been established for cluster headache.

Zembrace SymTouch

FDA-approved Indications

Zembrace SymTouch is indicated for the acute treatment of migraine with or without aura in adults.

Limitations 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 Zembrace SymTouch, reconsider the diagnosis before Zembrace SymTouch is administered to treat any subsequent attacks.
- Zembrace SymTouch injection is not indicated for the prevention of migraine attacks.

Zolmitriptan Orally Disintegrating Tablets (ODT)

FDA-approved Indications

Zolmitriptan orally disintegrating tablets are indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use

- Only use zolmitriptan if a clear diagnosis of migraine has been established. If a patient has no response to zolmitriptan treatment for the first migraine attack, reconsider the diagnosis of migraine before zolmitriptan is administered to treat any subsequent attacks.
- Zolmitriptan orally disintegrating tablets are not indicated for the prevention of migraine attacks.
- Safety and effectiveness of zolmitriptan have not been established for cluster headache.

Zomig Nasal Spray

FDA-approved Indications

Zomig nasal spray is indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

Limitations of Use

- Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine

before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks.
- Safety and effectiveness of Zomig have not been established for cluster headache.
- Not recommended in patients with moderate or severe hepatic impairment.

Compendial Uses

Acute treatment of cluster headache[19]

Zomig Tablets

FDA-approved Indications

Zomig is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use

- Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks.
- Zomig is not indicated for the prevention of migraine attacks.
- Safety and effectiveness of Zomig have not been established for cluster headache.

Coverage Criteria

Cluster Headache

Authorization may be granted when the requested drug is being prescribed for the treatment of cluster headache when ALL of the following criteria are met:

- The patient does NOT have confirmed or suspected cardiovascular OR cerebrovascular disease, OR uncontrolled hypertension.
- The request is for sumatriptan injection, sumatriptan nasal spray, OR zolmitriptan nasal spray (e.g., Imitrex Injection, Imitrex Nasal Spray, Onzetra Xsail, Tosymra, Zomig Nasal Spray).
- The patient meets ONE of the following:
  - The requested drug is NOT being used concurrently with another triptan 5-HT1 agonist.
  - The requested drug is being used concurrently with another triptan 5-HT1 agonist, AND the patient requires more than one triptan 5-HT1 agonist due to clinical need for differing routes of administration.

Migraine Headache

Authorization may be granted when the requested drug is being prescribed for the diagnosis of migraine headache when ALL of the following criteria are met:

- The patient does NOT have confirmed or suspected cardiovascular OR cerebrovascular disease, OR uncontrolled hypertension.
- Medication overuse headache has been considered AND ruled out.
- The patient meets ONE of the following:
    - The patient is currently using migraine prophylactic therapy. [NOTE: Examples of prophylactic therapy are divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, candesartan, amitriptyline, venlafaxine, erenumab, fremanezumab, galcanezumab, eptinezumab, rimegepant, atogepant.]
    - The patient is unable to take migraine prophylactic therapies due to an inadequate treatment response, intolerance or contraindication. [NOTE: Examples of prophylactic therapy are divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, candesartan, amitriptyline, venlafaxine, erenumab, fremanezumab, galcanezumab, eptinezumab, rimegepant, atogepant.]
- The patient meets ONE of the following:
    - The requested drug is NOT being used concurrently with another triptan 5-HT1 agonist.
    - The requested drug is being used concurrently with another triptan 5-HT1 agonist, AND the patient requires more than one triptan 5-HT1 agonist due to clinical need for differing routes of administration.

Quantity Limits Apply

Please Note: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Utilize higher strength when available and applicable.

Medication	**Strength**	**Maximum dose per 24 hours**	**1 Month Limit**	**3 Months Limit**
almotriptan	6.25 mg	N/A	18 tablets / 25 days	54 tablets / 75 days
almotriptan	12.5 mg	2 tablets 25 mg	18 tablets / 25 days	54 tablets / 75 days
Frova (frovatriptan)	2.5 mg	3 tablets 7.5 mg	27 tablets / 25 days	81 tablets / 75 days

Medication	Strength	Maximum dose per 24 hours	1 Month Limit	3 Months Limit
Imitrex Injection (sumatriptan) single dose vials	6 mg	2 injections 12 mg	18 vials (9 mL) / 25 days	55 vials (27.5 mL) / 75 days
Imitrex Injection (sumatriptan) syringes STATdose / Refill	4 mg	3 injections 12 mg	27 syringes (13.5 mL) / 25 days	81 syringes (40.5 mL) / 75 days
Imitrex Injection (sumatriptan) syringes STATdose / Refill	6 mg	2 injections 12 mg	18 syringes (9 mL) / 25 days	54 syringes (27 mL) / 75 days
Imitrex Nasal Spray (sumatriptan)	5 mg	N/A	36 units / 25 days	108 units / 75 days
Imitrex Nasal Spray (sumatriptan)	20 mg	2 sprays 40 mg	18 units / 25 days	54 units / 75 days
Imitrex Tablets (sumatriptan)	25 mg, 50 mg	N/A	18 tablets / 25 days	54 tablets / 75 days
Imitrex Tablets (sumatriptan)	100 mg	2 tablets 200 mg	18 tablets / 25 days	54 tablets / 75 days
Maxalt (rizatriptan)	10 mg	3 tablets 30 mg	27 tablets / 25 days	81 tablets / 75 days
Maxalt-MLT (rizatriptan)	10 mg	3 tablets 30 mg	27 tablets / 25 days	81 tablets / 75 days
naratriptan	1 mg	N/A	18 tablets / 25 days	54 tablets / 75 days
naratriptan	2.5 mg	2 tablets 5 mg	18 tablets / 25 days	54 tablets / 75 days
Onzetra Xsail (sumatriptan)	11 mg	4 nosepieces 44 mg	32 nosepieces / 25 days (2 kits, 16 pouches)	96 nosepieces / 75 days (6 kits, 48 pouches)
Relpax (eletriptan)	20 mg	N/A	18 tablets / 25 days	54 tablets / 75 days
Relpax (eletriptan)	40 mg	2 tablets 80 mg	18 tablets / 25 days	54 tablets / 75 days
rizatriptan	5 mg	N/A	27 tablets / 25 days	81 tablets / 75 days

Medication	Strength	Maximum dose per 24 hours	1 Month Limit	3 Months Limit
rizatriptan ODT	5 mg	N/A	27 tablets / 25 days	81 tablets / 75 days
Tosymra (sumatriptan)	10 mg	3 sprays 30 mg	24 units / 25 days	72 units / 75 days
Treximet (sumatriptan/naproxen)	85 mg/500 mg	1-2 tablets 170 mg/1000 mg	18 tablets / 25 days	54 tablets / 75 days
Zembrace SymTouch (sumatriptan)	3 mg	4 injections 12 mg	36 autoinjectors (18 mL) / 25 days	108 autoinjectors (54 mL) / 75 days
zolmitriptan ODT	2.5 mg	N/A	18 tablets / 25 days	54 tablets / 75 days
zolmitriptan ODT	5 mg	2 tablets 10 mg	18 tablets / 25 days	54 tablets / 75 days
Zomig Nasal Spray (zolmitriptan)	2.5 mg	N/A	18 units / 25 days	54 units / 75 days
Zomig Nasal Spray (zolmitriptan)	5 mg	2 sprays 10 mg	18 units / 25 days	54 units / 75 days
Zomig Tablets (zolmitriptan)	2.5 mg	N/A	18 tablets / 25 days	54 tablets / 75 days
Zomig Tablets (zolmitriptan)	5 mg	2 tablets 10 mg	18 tablets / 25 days	54 tablets / 75 days

Duration of Approval (DOA)

- 903-J: DOA: 12 months
- 1-J: DOA: 36 months

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