

Sumatriptan injections
(Imitrex®; Zembrace® SymTouch®)

Place of Service
Office Administration
Home Infusion Administration
Outpatient Facility Infusion
Administration
Infusion Center Administration
Self-Administration

Imitrex®,
HCPCS: J3030 per 6 mg

Zembrace® SymTouch®
HCPCS: J3490

Zembrace® SymTouch® NDCs:
67857-0809-38, 67857-0809-37,
00245-0809-38, 00245-0809-89

Conditions listed in policy (see criteria for details):

- [Acute migraine](#)
- [Cluster headaches](#)

AHFS therapeutic class: Selective Serotonin Agonist

Mechanism of action: Sumatriptan is a selective agonist of vascular serotonin (5-hydroxytryptamine, 5HT) type1 receptors.

(1) Special Instructions and Pertinent Information

If member has a Prescription Benefit, please refer cases to Pharmacy Services for prior authorization.

If covered under the Medical Benefit, please submit clinical information for prior authorization review. Please include medical rationale why medication cannot be home self-administered.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Imitrex® or Zembrace™ SymTouch™ for conditions NOT LISTED in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acute migraine

1. One of the following:

- a. Patient experiences **≤ 8 headache days per month**, cover if meets all:
 - i. The total number of injections requested per month does not exceed the amount needed to treat the number of headache days experienced per month (authorization must default to appropriate package size), **AND**
 - ii. Patient is not taking sumatriptan injection along with another triptan, Imitrex nasal spray, or an ergot-type drug (ex: DHE, ergotamine, Cafergot, Migranal, Trudhesa)

OR

- b. Patient experiences **> 8 headache days per month**, cover if meets all:
 - i. Patient is currently being followed by a neurologist or at a headache clinic, **AND**
 - ii. The total number of injections requested per month does not exceed the amount needed to treat the number of headache days experienced per month (authorization must default to appropriate package size), **AND**
 - iii. Patient is not taking sumatriptan injection along with another triptan, Imitrex nasal spray, or an ergot-type drug (ex: DHE, ergotamine, Cafergot, Migranal, Trudhesa), **AND**
 - iv. Patient is currently taking a migraine prophylactic medication including an anticonvulsant, or antidepressant, or beta-blockers **OR** contradiction to all agents including divalproex, valproate, topiramate, amitriptyline, venlafaxine, atenolol, metoprolol, nadolol, propranolol, and timolol

AND

2. **For Zembrace® SymTouch® only:** Inadequate response, intolerable side effects or contraindication with preferred injectable sumatriptan (Imitrex) formulations.

Covered Doses

Sumatriptan injection dose taken within a 24-hour period not to exceed 12 mg

- For Sumatriptan injection (Imitrex), Prior Authorization required for greater than 8 kits (16 UOS) per month
- For Zembrace® SymTouch®, Prior Authorization required for all requests

Coverage Period

Indefinite

ICD-10:

G43.001- G43.819, G43.A01-G43.D19

Cluster headaches

1. Recommended by neurologist or headache specialist, **AND**
2. Patient is currently taking a prophylactic medication recognized for use in cluster headaches from the following list: prednisone, dexamethasone, verapamil, lithium or topiramate OR contradiction to all agents above recognized as being efficacious for cluster headache prophylaxis, **AND**
3. Patient is not taking sumatriptan injection along with another triptan, Imitrex nasal spray, or an ergot-type drug (ex: DHE, ergotamine, Cafergot, Migranal, Trudhesa), **AND**
4. **For Zembrace SymTouch only:** Inadequate response, intolerable side effects or contraindication with formulary injectable sumatriptan (Imitrex) formulations.

Covered Doses

Sumatriptan injection dose taken within a 24-hour period not to exceed 12 mg

- For Sumatriptan injection (Imitrex), Prior Authorization required for greater than 8 kits (16 UOS) per month
- For Zembrace™ SymTouch™, Prior Authorization required for all requests

Coverage Period

3 months

ICD-10:

G44.001, G44.009

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Imitrex® or Zembrace™ for conditions NOT LISTED in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Imitrex (HCPCS J3030): up to 16 units of service (UOS) per month
(Prior Authorization required for greater than 16 UOS per month)

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

Imitrex (J3030):

- STATdose System Kit: 4 mg (NDC 0173-0739-00)
 - 1 STATdose Pen
 - 2 prefilled single-dose syringe cartridges
 - 1 carrying case
- STATdose System Kit: 6 mg (NDC 0173-0479-00)
 - 1 STATdose Pen
 - 2 prefilled single-dose syringe cartridges
 - 1 carrying case

Commercial

Sumatriptan (Imitrex®, Zembrace® SymTouch®)

- Two - 4 mg single-dose prefilled syringe cartridge for Imitrex STATdose System (NDC 0173-0739-02)
- Two - 6 mg single-dose prefilled syringe cartridge for Imitrex STATdose System (NDC 0173-0478-00)
- 6 mg/0.5 ml vial solution for injection

Sumatriptan succinate (J3030):

- System Kit: 4 mg
 - 1 Pen
 - 2 prefilled single-dose syringe cartridges
- System Kit: 6 mg
 - 1 Pen
 - 2 prefilled single-dose syringe cartridges
- Two - 4 mg/0.5 ml prefilled syringe auto-injector
- Two - 6 mg/0.5 ml prefilled syringe auto-injector
- Two - 4 mg/0.5 ml solution refill cartridge
- Two - 6 mg/0.5 ml solution refill cartridge
- 6 mg/0.5 ml vial solution for injection

Zembrace SymTouch:

- 3 mg sumatriptan in 0.5 mL prefilled, ready-to-use, single dose, disposable auto-injector
- NDCs: 67857-0809-38, 67857-0809-37, 00245-0809-38, 00245-0809-89

Table 1. AAN 2012 Classification of Migraine Preventative Therapies.

Level A Established efficacy	Level B Probably effective	Level C Possibly effective	Level U Inadequate or conflicting data to support or refute use	Other Possibly or probably ineffective
Antiepileptics: <ul style="list-style-type: none"> • Divalproex sod • Valproate • Topiramate Beta blockers: <ul style="list-style-type: none"> • Metoprolol • Propranolol • Timolol 	Antidepressants: <ul style="list-style-type: none"> • Amitriptyline • Venlafaxine Beta blockers: <ul style="list-style-type: none"> • Atenolol • Nadolol 	ACE Inhibitors: <ul style="list-style-type: none"> • Lisinopril Alfa-agonists: <ul style="list-style-type: none"> • Clonidine • Guanfacine Antiepileptics: <ul style="list-style-type: none"> • Carbamazepine Antihistamines: <ul style="list-style-type: none"> • Cyproheptadine ARBs: <ul style="list-style-type: none"> • Candesartan Beta blockers: <ul style="list-style-type: none"> • Nebivolol • Pindolol 	Antidepressants: <ul style="list-style-type: none"> • Fluvoxamine • Fluoxetine Antiepileptics: <ul style="list-style-type: none"> • Gabapentin Antithrombotics: <ul style="list-style-type: none"> • Acenocoumarol • Coumadin Beta Blockers: <ul style="list-style-type: none"> • Bisoprolol Carbonic anhydrase inhibitor: <ul style="list-style-type: none"> • Acetazolamide Muscle relaxants: <ul style="list-style-type: none"> • Cycloclate TCA: <ul style="list-style-type: none"> • Protriptyline 	Antiepileptics: <ul style="list-style-type: none"> • Lamotrigine • Oxcarbazepine³ ARBs: <ul style="list-style-type: none"> • Telmisartan Beta blockers: <ul style="list-style-type: none"> • Acebutolol Benzodiazepine: <ul style="list-style-type: none"> • Clonazepam NSAID: <ul style="list-style-type: none"> • Nabumetone TCA/Other: <ul style="list-style-type: none"> • Clomipramine

ACE = ace inhibitor; ARB = angiotensin receptor blocker; TCA = tricyclic antidepressant

(6) References

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- Evers S, Afra J, Frese A, Goadsby PJ, Linde M, May A, Sandor PS. Cluster headache and other trigemino-autonomic cephalgias. European Federation of Neurological Societies - Medical Specialty SocietyIn: Gilhus NE, Barnes MP, Brainin M, editor(s). European handbook of neurological management. 2nd ed. Vol. 1. Oxford (UK): Wiley-Blackwell; 2011. p. 179-90
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(7) Policy Update

Date of last review: 3Q2022

Date of next review: 3Q2023

Changes from previous policy version:

- No clinical change to policy following routine annual review

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*