**[TEMPLATE]**

[The following template is provided as a resource and is for informational purposes only. This template is not intended to provide reimbursement or legal advice.]

**Letter of Medical Necessity**

 **Tosymra® (Sumatriptan Nasal Spray) 10 mg**

[Date]

ATTN:

[Health Plan]

[Contact name]

RE: [Patient]

Date of birth: [Patient DOB]

[Policy #] [Group #]

To whom it may concern:

I am writing on behalf of [Patient] **to request approval of Tosymra (sumatriptan nasal spray) 10 mg** as a non-oral treatment for acute migraine.

[Patient] is an adult and has been in my care for the acute treatment of migraine with or without aura since [date]. Based on my clinical judgment, Tosymra is specifically medically necessary for [Patient] because:

*[Select your rationale for prescribing Tosymra from the list below; delete items not applicable and add additional rationale as applicable for your patient].*

* [Patient] has migraines with nausea/vomiting that prohibit the use of oral triptans. *AHS recommends a non-oral triptan for such patients.1,2*
* [Patient] has [morning OR rapid-onset] migraines for which an oral triptan is NOT appropriate due to slow onset of action. *AHS recommends a non-oral triptan for morning or rapid-onset migraines,2* to provide rapid pain relief and minimize migraine-associated disability.Tosymra achieves peak concentration 8X faster than Imitrex Nasal Spray3 and provides onset of pain relief in as few as 10 minutes, the same as injectable sumatriptan and more rapidly than oral sumatriptan.4-6
* [Patient] has migraines of varying presentation, including some with [nausea/vomiting, morning onset, rapid onset], requiring a non-oral AND oral triptan to manage all migraine types. *AHS recommends a non-oral triptan for such patients.1,2*
* [Patient] is UNABLE to swallow solid oral dosage forms and requires a non-oral treatment.
* [Patient] has failed generic sumatriptan nasal spray due to [slow onset of pain relief OR intolerable side effect OR other reason].
* [Patient] exhibits symptoms consistent with migraine-associated gastroparesis, which compromises the ability to absorb oral medications.
* [Patient] is at risk of progressing to chronic migraine if adequate control of migraines is not established.
* [Other]

[Patient] is a [age]-year-old [male/female] who suffers from acute migraines [ICD-10-CM diagnosis code]

with a frequency of [number] headache days per month. [Patient] was referred to me for care by [Referring provider, specialty]. My current treatment plan for [Patient] includes [current treatment(s), dosage, frequency]. [Patient name] has been on this treatment plan since [date].

My patient has previously tried and failed:

* ORAL [triptan name]: due to migraine-associated nausea/vomiting. *AHS recommends a non-oral triptan for such patients.1*
* ORAL [triptan name]: provided inconsistent relief and therefore requires a non-oral treatment as a self-administered rescue medication.
* ORAL [triptan name]: ineffective for [morning OR rapid-onset] migraines due to [slow onset of pain relief OR other reason]. *AHS recommends a non-oral triptan for morning or rapid-onset migraines,2* to provide rapid-onset pain relief and minimize migraine-associated disability.Tosymra achieves peak concentration 8X faster than Imitrex Nasal Spray3 and provides onset of pain relief in as few as 10 minutes, the same as injectable sumatriptan and more rapidly than oral sumatriptan.4-6

My office can be contacted at [phone number/email address] if additional information is required to approve this request. Thank you in advance for enabling me to meet my patient’s treatment goals by allowing access to Tosymra Nasal Spray.

Sincerely,

[Provider name, medical specialty, National Provider Identifier number]

[Provider address]

[Provider phone number]

[Provider fax number]

[Provider email]

**Enclosures** [suggested]:

[Relevant patient medical records]

**References**

1. Ailani, J, Burch, RC, Robbins, MS; the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021; 61: 1021– 1039. <https://doi.org/10.1111/head.14153>.
2. <https://americanheadachesociety.org/wp-content/uploads/2018/05/John_Rothrock_and_Deborah_Friedman_-_Triptans.pdf>. Accessed Jan 2023.
3. Munjal S, et al. A randomized trial comparing the pharmacokinetics, safety, and tolerability of DFN-02, an intranasal sumatriptan spray containing a permeation enhancer, with intranasal and subcutaneous sumatriptan in healthy adults. *Headache*. 2016;56(9):1455-1465.
4. Tosymra [package insert]. Chatham, NJ: Tonix Medicines: 2021.
5. Mathew NT, et al. Dose ranging efficacy and safety of subcutaneous sumatriptan in the acute treatment of migraine. US Sumatriptan Research Group. *Arch Neurol*. 1992;49(12):1271-1276.
6. Wendt J, et al. A randomized, double-blind, placebo-controlled trial of the efficacy and tolerability of a 4-mg dose of subcutaneous sumatriptan for the treatment of acute migraine attacks in adults. *Clinical Therapeutics*. 2006;28(4):517-526.

[Tosymra is a registered trademark of Tonix Medicines]

[PM-002232.02]

# IMPORTANT SAFETY INFORMATION

Tosymra® is contraindicated in patients with:

* Ischemic Coronary Artery Disease (CAD) or coronary artery vasospasm (including Prinzmetal’s angina)
* Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders
* History of stroke or transient ischemic attack or history of hemiplegic or basilar migraine
* Peripheral vascular disease
* Ischemic bowel disease
* Uncontrolled hypertension
* Recent (i.e., within 24 hours) use of ergotamine-containing medication, ergot-type medication, or another 5-HT1 agonist
* Concurrent or recent (within 2 weeks) use of a monoamine oxidase (MAO)-A inhibitor
* Known hypersensitivity to sumatriptan (angioedema and anaphylaxis seen)
* Severe hepatic impairment

There have been rare reports of serious cardiac adverse reactions, including acute myocardial

infarction, occurring within a few hours following administration of sumatriptan. Some of these reactions occurred in patients without known CAD. Tosymra, like other 5-HT1 agonists, may cause coronary artery vasospasm. Perform a cardiovascular evaluation in triptan-naive patients who have multiple cardiovascular risk factors prior to receiving Tosymra. For patients with multiple cardiovascular risk factors who have a negative cardiovascular evaluation, consider administering the first dose of Tosymra in a medically supervised setting and performing an ECG immediately following administration. For such patients, consider periodic cardiovascular evaluation in intermittent long-term users of Tosymra.

Life-threatening disturbances of cardiac rhythm, leading to death in some cases, have been reported within a few hours following the administration of 5-HT1 agonists. Discontinue Tosymra if any of these cardiovascular disturbances occur.

Cerebral hemorrhage, subarachnoid hemorrhage, and stroke have occurred in patients treated with 5-HT1 agonists, and some have resulted in fatalities. Discontinue Tosymra if these occur.

Sensations of tightness, pain, pressure, and heaviness in the precordium, throat, neck, and jaw commonly occur after treatment with sumatriptan injection and are usually non-cardiac in origin.

Tosymra may cause non-coronary vasospastic reactions, such as peripheral vascular ischemia, gastrointestinal vascular ischemia and infarction, splenic infarction, and Raynaud’s syndrome.

Overuse of acute migraine drugs may lead to medication overuse headache. Detoxification of patients and treatment of withdrawal symptoms may be necessary.

Serotonin syndrome may occur with Tosymra, particularly during co-administration with

selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors, tricyclic antidepressants, and MAO inhibitors. Discontinue Tosymra if serotonin syndrome is suspected.

Significant elevation in blood pressure, including hypertensive crisis, has been reported on rare occasions in patients treated with 5-HT1 agonists, including patients without a history of hypertension. Monitor blood pressure in patients treated with Tosymra.

Seizures have been reported following administration of sumatriptan. Some have occurred in patients with either a history of seizures or concurrent conditions predisposing to seizures.

Tosymra should be used with caution in patients with a history of epilepsy or conditions associated with a lowered seizure threshold.

Most common adverse reactions (≥5% and > placebo) with sumatriptan injection were tingling, dizziness/vertigo, warm/hot sensation, burning sensation, feeling of heaviness, pressure

sensation, flushing, feeling of tightness, and numbness.

This safety information is not comprehensive. Please refer to the Tosymra full [Prescribing Information](https://www.tosymra.com/wp-content/uploads/2023/12/Tosymra-Patient-Information_USL.pdf), [Patient Information](https://www.tosymra.com/wp-content/uploads/2023/12/Tosymra-Patient-Information_USL.pdf), and [Instructions for Use.](https://www.tosymra.com/wp-content/uploads/2023/12/Tosymra-Instructions-for-Use-1.pdf) You can also visit [www.tonixpharma.com](https://www.tonixpharma.com/) or call 1-888-869-7633.

You are encouraged to report suspected adverse reactions to Tonix Medicines at 1-888-869-7633 or to the FDA by visiting [www.fda.gov/medwatch](https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program) or calling 1-800-FDA-1088.

# INDICATION AND USAGE

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.