**[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**

 **Zembrace® SymTouch® (Sumatriptan Injection) 3 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 Zembrace SymTouch (sumatriptan injection) 3 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, Zembrace SymTouch is specifically medically necessary for [Patient] because:

*[Select your rationale for prescribing Zembrace SymTouch 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.Zembrace SymTouch provides onset of pain relief in as few as 10 minutes.3
* [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 an adequate trial of generic sumatriptan injection [4 mg or 6 mg] due to [intolerable dose-related side effect]. Zembrace SymTouch is the only autoinjector to offer a lower, 3 mg dose.
* [Patient] has failed an adequate trial of generic sumatriptan injection [4 mg or 6 mg] due to [a severe injection site reaction]. Zembrace SymTouch offers the smallest needle in the sumatriptan autoinjector class and delivers a less concentrated sumatriptan solution.4
* [Patient] exhibits symptoms consistent with migraine-associated gastroparesis, which compromises the ability to absorb oral medications. Therefore, [Patient] requires an injectable therapy that bypasses the GI tract.
* [Patient] is at risk of progressing to chronic migraine if adequate control of migraines is not established.
* [Patient] experiences migraine-associated cognitive dysfunction, which requires the patient to receive Zembrace SymTouch because it needs no assembly prior to use and has a simple two-step administration process that the patient has been adequately trained on by my office staff.
* [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. [He/She] was referred to me for care by [Referring provider, specialty]. My current treatment plan for [Patient name] 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]: was ineffective for [morning OR rapid-onset] migraines due to [slow onset of pain relief OR other reason]. *AHS recommends a non-oral triptan morning or rapid-onset migraines,2* to provide rapid-onset pain relief and minimize migraine-associated disability.Zembrace SymTouch provides onset of pain relief in as few as 10 minutes.3

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 Zembrace SymTouch.

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 Oct 2022.
3. Zembrace SymTouch [package insert]. Catham, NJ: Tonix Medicines: 2021.
4. Data on file. Catham, NJ: Tonix Medicines: 2023.

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[PM-002235.02]

**IMPORTANT SAFETY INFORMATION**

Zembrace® SymTouch® is contraindicated in patients with:

* Ischemic Coronary Artery Disease (CAD) (angina pectoris, history of myocardial infarction, or documented silent ischemia) 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 (TIA) or history of hemiplegic or basilar migraine because these patients are at a higher risk of stroke.
* Peripheral vascular disease
* Ischemic bowel disease
* Uncontrolled hypertension
* Recent (i.e., within 24 hours) use of ergotamine-containing medication, ergot-type medication (such as dihydroergotamine or methysergide), or another 5-hydroxytryptamine1 (5-HT1) agonist
* Concurrent administration of an MAO-A inhibitor or recent (within 2 weeks) use of an 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 injection. Some of these reactions occurred in patients without known CAD. 5-HT1 agonists, including Zembrace SymTouch, may cause coronary artery vasospasm (Prinzmetal’s angina), even in patients without a history of CAD.

Perform a cardiovascular evaluation in triptan-naive patients who have multiple cardiovascular risk factors prior to receiving Zembrace SymTouch. For patients with multiple cardiovascular risk factors who have a negative cardiovascular evaluation, consider administering the first dose of Zembrace SymTouch in a medically supervised setting and performing an electrocardiogram (ECG) immediately following Zembrace SymTouch. For such patients, consider periodic cardiovascular evaluation in intermittent long-term users of Zembrace SymTouch.

Life-threatening disturbances of cardiac rhythm, including ventricular tachycardia and ventricular fibrillation leading to death, have been reported within a few hours following the administration of 5-HT1 agonists. Discontinue Zembrace SymTouch if these disturbances 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. However, perform a cardiac evaluation if these patients are at high cardiac risk.

Cerebrovascular events including cerebral hemorrhage, subarachnoid hemorrhage, and stroke have occurred in patients treated with 5-HT1 agonists, and some have resulted in fatalities. Discontinue Zembrace SymTouch if a cerebrovascular event occurs.

Zembrace SymTouch 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 exacerbation of headache (medication overuse headache). Detoxification of patients, including withdrawal of the overused drugs, and treatment of withdrawal symptoms may be necessary.

Serotonin syndrome may occur with Zembrace SymTouch, particularly during co-administration with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and MAO inhibitors. Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination), and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Discontinue Zembrace SymTouch if serotonin syndrome is suspected.

Significant elevation in blood pressure, including hypertensive crisis with acute impairment of organ systems, 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 Zembrace SymTouch.

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. Zembrace SymTouch 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) were injection site reactions, tingling, dizziness/vertigo, warm/hot sensation, burning sensation, feeling of heaviness, pressure sensation, flushing, feeling of tightness, and numbness/paresthesia.

This safety information is not comprehensive. Please refer to the Zembrace SymTouch full [Prescribing Information](https://www.zembrace.com/wp-content/uploads/2019/10/Zembrace-Patient-Information_USL.pdf), [Patient Information](https://zembrace.graphicadevsite.com/wp-content/uploads/2019/10/Zembrace-Patient-Information-Sheet.pdf), and [Instructions for Use](https://www.zembrace.com/wp-content/uploads/2019/10/Zembrace-Instructions-for-Use.pdf). You can also visit [www.tonixpharma.com](https://www.tonixpharma.com/) or call 1-888-650-3789.

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](http://www.fda.gov/medwatch) or calling 1-800-FDA-1088.

#### INDICATION AND USAGE

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 is not indicated for the prevention of migraine attacks.