PRIOR AUTHORIZATION CRITERIA

DRUG CLASS 5-HT1 AGONISTS, COMBINATIONS (ALL DOSAGE FORMS)

BRAND NAME* (generic)

AMERGE (naratriptan)

AXERT (almotriptan)

FROVA (frovatriptan)

IMITREX (sumatriptan)

MAXALT/MAXALT-MLT (rizatriptan)

ONZETRA XSAIL (sumatriptan)

RELPAX (eletriptan)

SUMAVEL DosePro (sumatriptan)

TOSYMRA (sumatriptan)

TREXIMET (sumatriptan/naproxen)

ZEMBRACE SYMTOUCH (sumatriptan)

ZOMIG / ZOMIG-ZMT (zolmitriptan)

Status: CVS Caremark Criteria Ref # 1-J
Type: Post Limit Prior Authorization Ref # MMT 903-J

*Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.

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FDA-APPROVED INDICATIONS

Amerge

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

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

Axert

Adults: Axert (almotriptan malate) is 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: Axert is 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).

Axert 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 Axert, the diagnosis of migraine should be reconsidered before Axert is administered to treat any subsequent attacks. In adolescents age 12 to 17 years, efficacy of Axert on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Axert is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of Axert have not been established for cluster headache which is present in an older, predominantly male population.

Frova

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

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

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.

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 is not indicated for the prevention of migraine or cluster headache attacks.

Imitrex Nasal Spray and Imitrex Tablets

Imitrex Nasal Spray and Imitrex Tablets are indicated for the acute treatment of migraine with or without aura in adults. 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-MLT and Maxalt

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

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.

Onzetra Xsail

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

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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.

Relpax

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

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 treatment of subsequent attacks with Relpax. 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.

Sumavel DosePro

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

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

Tosymra

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.

Treximet

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

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

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

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.

Zomig Nasal Spray

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.

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.

Zomig Tablets and Zomig-ZMT

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

Zomig should only be used 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.

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Compendial Uses¹⁶
Imitrex Nasal Spray
Acute treatment of cluster headache
Onzetra Xsail
Acute treatment of cluster headache
Tosymra
Acute treatment of cluster headache
Zomig Nasal Spray

Acute treatment of cluster headache

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

• The patient does <u>not</u> have confirmed or suspected cardiovascular or cerebrovascular disease, or uncontrolled hypertension

AND

- The patient has a diagnosis of migraine headache AND
 - The patient is currently using migraine prophylactic therapy or unable to take migraine prophylactic therapies due to inadequate response, intolerance or contraindication
 [Note: examples of prophylactic therapy are divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, venlafaxine.]
 AND
 - o Medication overuse headache has been considered and ruled out

OR

• The request is for sumatriptan injection, sumatriptan nasal spray, or zolmitriptan nasal spray (e.g., Imitrex Injection, Imitrex Nasal Spray, Onzetra Xsail, Sumavel DosePro, Tosymra, Zomig NS) for the treatment of cluster headache

Quantity Limits apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Amerge, Axert, Frova, Imitrex, Maxalt/Maxalt-MLT, Onzetra Xsail, Relpax, Sumavel DosePro, Tosymra, Treximet, Zembrace SymTouch, and Zomig/Zomig-ZMT are indicated for the acute treatment of migraine attacks with or without aura. Axert, Treximet, and Zomig Nasal Spray are indicated for the acute treatment of migraine headache pain with or without aura in pediatric patients 12 years of age and older. Maxalt/Maxalt-MLT are indicated for the acute treatment of migraine with or without aura in pediatric patients 6 to 17 years old. Imitrex Injection and Sumavel DosePro are indicated for the acute treatment of cluster headache episodes. Additionally, Imitrex Nasal Spray, Onzetra Xsail, Tosymra nasal spray, and Zomig Nasal Spray can be used for the acute treatment of cluster headache based on the levels of evidence for safety and efficacy. 16-18, 22-25

Triptan therapy is contraindicated in patients with confirmed or suspected cardiovascular disease (e.g., ischemic or vasospastic coronary artery disease) or cerebrovascular disease (e.g., stroke or transient ischemic attacks), and in patients with uncontrolled hypertension.

For prevention of migraine headache, the American Academy of Neurology and the American Headache Society 2012 guideline update recommendations state that the following medications are established as effective and should be offered for migraine prevention: β -adrenergic blocking agents, metoprolol, propranolol, timolol; and antiepileptic drugs (AEDs), divalproex sodium, topiramate, sodium valproate. Additionally the following medications are probably effective: antidepressants, amitriptyline, venlafaxine; and β -adrenergic blocking agents, atenolol, nadolol and should be considered for migraine prevention. Efficacy and safety of individual agents, even within the same class of drugs, may vary among patients therefore, if the patient fails one preventive medication, others should be tried as failure of one agent does not rule out success with another one. $^{16-20}$ The Institute for Clinical Systems Improvement (ICSI) headache guidelines state that preventive therapy should be considered for all patients, and the American Academy of Neurology (AAN) guidelines

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recommend preventive medications when there is either an impact on life and acute therapy is not working or where headache frequency can lead to medication overuse headache. Additionally, a position statement from the American Headache Society states that patients should be considered for preventive treatment in any of the following situations: attacks significantly interfere with patients' daily routines despite acute treatment; frequent attacks (≥ 4 migraine headache days); a contraindication to, failure, or overuse of acute treatments; adverse events with acute treatments; or patient preference. Therefore, patients with migraine headache must be currently taking or had an inadequate response, intolerance, or contraindication to prophylactic therapies.

Cluster headache is a most painful form of primary headache lasting 15 to 180 minutes, occurring from once every other day to eight times per day, and associated with one or more of various ipsilateral symptoms (conjunctival injection, lacrimation, nasal congestion, rhinorrhea, forehead and facial sweating, miosis, ptosis or eyelid edema). Given the severity, fast onset and short time to peak intensity of this type of headache, treatment should be rapid and effective. Due to the slower absorption rate and delayed onset of action, oral medications are not an appropriate choice for treatment of cluster headache. The treatments of choice for acute cluster headache attacks are oxygen, and intranasal or subcutaneous sumatriptan or intranasal zolmitriptan, or a combination of both. Results injection, Imitrex Nasal Spray, Onzetra Xsail, Sumavel DosePro, Tosymra nasal spray, and Zomig Nasal Spray will also be considered for patients with cluster headache who require quantities in excess of the initial limit.

Frequent use of acute migraine drugs (e.g. ergotamine, triptans, opioids, or combination of these drugs for 10 or more days per month) may lead to exacerbation of headache (medication overuse headache). To decrease the risk of medication-overuse headache ("rebound headache" or "drug-induced headache") many experts limit acute therapy to two headache days per week on a regular basis. Drug treatment of acute headache should generally not exceed more than two days per week on a regular basis. More frequent treatment other than this may result in medication-overuse chronic daily headaches. Therefore, the prescriber must have considered and ruled out the diagnosis of medication overuse headache.

The limits are set at a quantity sufficient to treat 8 headaches per month and may allow for up to 9 headache days per month up to maximum recommended daily dosage, contingent on package dispensing requirements. 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 in the Post Limit Quantity chart.

Triptan Dosing Chart ¹⁻¹⁵				
Brand (generic) Name	Usual Dosage Range	Maximum Dose/24 hours		
Amerge (naratriptan) Tablets 1mg & 2.5mg	1 mg to 2.5 mg	5 mg		
Axert (almotriptan) Tablets 6.25mg & 12.5mg	6.25 mg to 12.5 mg	25 mg		
Frova (frovatriptan) Tablets 2.5mg	2.5 mg	7.5 mg		
Imitrex (sumatriptan) Injection				
6mg/0.5mL single-dose vial,	4 mg to 6 mg	12 mg		
4mg/0.5mL & 6mg/0.5mL prefilled syringe cartridges				
Imitrex (sumatriptan) Nasal Spray 5mg & 20mg	5 mg to 20 mg	40 mg		
Imitrex (sumatriptan) Tablets 25mg, 50mg & 100mg	25 mg to 100 mg	200 mg		
Maxalt/Maxalt-MLT (rizatriptan) Tablets 5mg & 10mg	5 mg to 10 mg	30 mg		
Onzetra Xsail (sumatriptan) Nosepieces 11mg	22 mg	44 mg		
Relpax (eletriptan) Tablets 20mg & 40mg	20 mg to 40 mg	80 mg		
Sumavel DosePro (sumatriptan) 4mg/0.5mL & 6mg/0.5mL	4 mg to 6 mg	12 mg		
Tosymra (sumatriptan) nasal spray 10mg	10 mg	30 mg		
Treximet (sumatriptan) Tablets 10mg/60mg	10 mg / 60 mg	10 mg / 60 mg (utilize higher strength)		
Treximet (sumatriptan) Tablets 85mg/500mg	85 mg / 500 mg	170 mg / 1000 mg		
Zembrace SymTouch (sumatriptan) Injection 3mg/0.5mL	3 mg	12 mg		
Zomig (zolmitriptan) Tablets 2.5mg & 5mg	1.25 mg to 5 mg			
Zomig-ZMT (zolmitriptan) Tablets 2.5mg & 5mg	2.5 mg to 5 mg	10 mg		
Zomig (zolmitriptan) Nasal Spray	2.5 mg to 5 mg			

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Written by: UM Development (LS)

Date written: 05/1998

Revised: 07/1998, 12/2000, 03/2001, 05/2001, 10/2001, 04/2002; (JG) 01/2003, 10/2003 (Zomig NS added); (RP) 1/2004; (JG) 07/2004, 07/2005; (AK) 02/2006; (CT) 06/2006; (AM) 07/2007, 04/2008 (2) (added Treximet), 07/2008, 07/2009; (KD) 07/2010; (CY) 05/2011,

07/2005; (AK) 02/2006; (C1) 06/2006; (AM) 07/2007, 04/2008 (2) (added Treximet), 07/2006, 07/2009; (KD) 07/2010; (C1) 05/2011 (10/2012 (extended duration); (RDP/TM) 04/2013, 08/2013, 10/2013, (TM) 12/2013 (add Zomig NS 2.5mg), (RP/TM) 05/2014, 10/2014 (add Sumavel 4mg), (TM) 05/2015, 09/2015 (remove Zecuity-Specialty), (TM) 02/2016 (add Onzetra Xsail and Zembrace SymTouch), (TM) 05/2016 (no clinical changes, add partial approval), (SE)11/2016 (added guidelines for approval grids), (TM) 12/2016 (rephrase question 7), 05/2017 (add mL to limits), 06/2017 (remove Alsuma); (KC) 06/2018 (non-clinical changes to

question 6), 02/2019 (added Tosymra), 06/2019, 08/2020 (updated denial reasons)

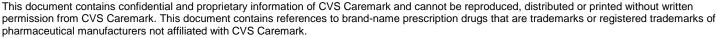
Reviewed: Medical Affairs 07/1998, 01/2001, 03/2001, 05/2001, 04/2002, 11/2003, 01/2004, 08/2004, 07/2005; (MM) 02/2006, 06/2006; (WF)

07/2007, 04/2008, 07/2008, 07/2009; 07/2010; (KP) 05/2011, 10/2012; (DC) 05/2013, (LS) 08/2013, 10/2013, (SS) 12/2013; (LMS) 05/2014, (DNC) 10/2014, (LCB) 05/2015, (GAD) 02/2016, (ME) 06/2017, (AN) 06/2018; (EPA) 02/2019; (LG) 06/2019 External Review: 07/2001, 05/2002, 12/2003, 04/2004, 10/2004, 11/2005, 10/2006, 12/2007, 12/2008, 12/2009, 09/2010, 10/2011,

10/2013, 10/2014, 10/2015, 10/2016, 10/2017, 10/2018, 02/2019 (FYI), 10/2019

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CRITE	RIA FOR APPROVAL		
1	Does the patient have confirmed or suspected cardiovascular or cerebrovascular disease, or uncontrolled hypertension?	Yes	No
2	Does the patient have a diagnosis of migraine headache? [If no, then skip to question 5.]	Yes	No
3	Is the patient currently using migraine prophylactic therapy or unable to take migraine prophylactic therapies due to inadequate response, intolerance or contraindication? [Note: examples of prophylactic therapy are divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, venlafaxine.]	Yes	No
4	Has medication overuse headache been considered and ruled out? [If yes, then skip to question 6.]	Yes	No
5	Is the request for sumatriptan injection, sumatriptan nasal spray, or zolmitriptan nasal spray (e.g., Imitrex Injection, Imitrex Nasal Spray, Onzetra Xsail, Sumavel DosePro, Tosymra, Zomig Nasal Spray) for the treatment of cluster headache?	Yes	No
6	Does the patient require MORE than the plan allowance PER MONTH of any of the following: A) 18 units of Amerge tablets (naratriptan), Axert tablets (almotriptan), Imitrex injection vials (sumatriptan), Imitrex STATdose 6 mg (sumatriptan), Imitrex nasal spray 20 mg (sumatriptan), Imitrex tablets (sumatriptan), Relpax tablets (eletriptan), Treximet tablets (sumatriptan/naproxen), Zomig tablets (zolmitriptan), Zomig-ZMT (zolmitriptan), Zomig Nasal Spray (zolmitriptan), B) 24 units of Tosymra (sumatriptan), C) 27 units of Frova tablets (frovatriptan), Imitrex STATdose 4 mg (sumatriptan), Maxalt tablets (rizatriptan), Maxalt-MLT (rizatriptan), Sumavel DosePro (sumatriptan), D) 32 units of Onzetra Xsail (sumatriptan), E) 36 units of Zembrace Symtouch (sumatriptan)? [Note: Coverage is provided up to an amount sufficient for treating up to eight headaches per month at the maximum daily dose of the prescribed drug.]	Yes	No
	[RPh Note: If yes, then deny and enter a partial approval per Post Limit Quantity Chart.]		

	Mapping Instructions (1-J)			
	Yes	No	DENIAL REASONS - DO NOT USE FOR MEDICARE PART D	
1.	Deny	Go to 2	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when the member does not have confirmed or suspected cardiovascular or cerebrovascular disease and does not have uncontrolled hypertension. Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you have confirmed or suspected cardiovascular or cerebrovascular disease or uncontrolled hypertension. [Short Description: Contraindication to drug]	
2.	Go to 3	Go to 5		
3.	Go to 4	Deny	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and	

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			circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when the member is using the requested medication for migraine headaches AND is currently using migraine prophylactic therapy or is unable to take migraine prophylactic therapies. Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you are using the requested medication for migraine headaches but are not currently using migraine prophylactic therapy and are able to take migraine prophylactic therapies. [Short Description: Migraine, no prophylaxis]
4.	Go to 6	Deny	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when the member has been assessed for medication overuse headache and this has been ruled out. Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you have not been assessed for medication overuse headache or this has not been ruled out. [Short Description: Migraine medication overuse not ruled out]
5.	Go to 6	Deny	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when the member is using the requested medication for migraine headaches or for cluster headaches, AND if being used for cluster headaches the requested medication is sumatriptan injection, sumatriptan nasal spray, or zolmitriptan nasal spray. Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you are not requesting the medication for migraine headaches or cluster headaches OR you are requesting the medication for cluster headaches and the requested medication is not sumatriptan injection, sumatriptan nasal spray, or zolmitriptan nasal spray. [Short Description: No approvable diagnosis]
6.	Deny RPh Note: For the denial verbiage, only include the drug the PA is for. Remove all the other drugs from	Approve, 36 months, See Post Limit Quantity Chart	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover an amount for treating eight headaches per month at a maximum daily dose up to: - 18 tablets/month of Amerge Tablets (naratriptan) - 18 tablets/month of Axert Tablets (almotriptan) - 27 tablets/month of Frova Tablets (frovatriptan) - 18 vials/month of Imitrex single-dose vial (sumatriptan) 6mg/0.5mL

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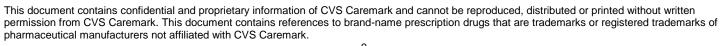


the verbiage.	- 18 syringe cartridges/month of Imitrex prefilled syringe
	(sumatriptan) 6mg/0.5mL
	- 27 syringe cartridges/month of Imitrex prefilled syringe
	(sumatriptan) 4mg/0.5mL
	- 18 nasal units/month of Imitrex Nasal Spray (sumatriptan) 20mg
	- 36 nasal units /month of Imitrex Nasal Spray (sumatriptan) 5mg
	- 18 tablets/month of Imitrex Tablets (sumatriptan)
	- 27 tablets/month of Maxalt/Maxalt-MLT Tablets (rizatriptan)
	- 32 nosepieces (2 kits or 16 pouches)/month of Onzetra Xsail
	Nosepiece (sumatriptan)
	- 18 tablets/month of Relpax Tablets (eletriptan)
	- 18 syringes/month Sumavel DosePro (sumatriptan) 6mg/0.5mL
	- 27 syringes /month of Sumavel DosePro (sumatriptan) 4mg/0.5mL
	- 24 nasal units/month of Tosymra nasal spray (sumatriptan) 10mg
	- 18 tablets/month of Treximet Tablets (sumatriptan) 85mg / 500mg
	- 18 tablets/month (27 tablets/3 months) of Treximet Tablets
	(sumatriptan) 10mg/60mg
	- 36 auto-injectors/month of Zembrace SymTouch (sumatriptan)
	- 18 tablets/month of Zomig/Zomig-ZMT Tablets (zolmitriptan)
	- 18 nasal units/month of Zomig Nasal Spray (zolmitriptan)
	You have been approved for the maximum quantity that your plan
	covers for a duration of 36 months. Your request for additional
	quantities of the requested drug and strength has been denied.
	[Short Description: Over max quantity]
	[[e.e. 2 acceptation of the max quarkey]

Guidelines for Approval (1-J)						
	Duration of Approval 36 Months/See Post Limit Quantity Chart					
Set 1 Set 2						
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)			
2	1	5	1			
3	6		2			
4	4 6					

	Mapping Instructions (MMT 903-J)				
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D		
1.	Deny	Go to 2	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when the member does not have confirmed or suspected cardiovascular or cerebrovascular disease and does not have uncontrolled hypertension. Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you have confirmed or suspected cardiovascular or cerebrovascular disease or uncontrolled hypertension. [Short Description: Contraindication to drug]		
2.	Go to 3	Go to 5			
3.	Go to 4	Deny	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be		

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			approved when the member is using the requested medication for migraine headaches AND is currently using migraine prophylactic therapy or is unable to take migraine prophylactic therapies. Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you are using the requested medication for migraine headaches but are not currently using migraine prophylactic therapy and are able to take migraine prophylactic therapies. [Short Description: Migraine, no prophylaxis]
4.	Go to 6	Deny	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when the member has been assessed for medication overuse headache and this has been ruled out. Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you have not been assessed for medication overuse headache or this has not been ruled out. [Short Description: Migraine medication overuse not ruled out]
5.	Go to 6	Deny	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when the member is using the requested medication for migraine headaches or for cluster headaches, AND if being used for cluster headaches the requested medication is sumatriptan injection, sumatriptan nasal spray, or zolmitriptan nasal spray. Based on the policy and the information we have, the request is denied. The request was denied because the information provided to us indicates that you are not requesting the medication for migraine headaches or cluster headaches OR you are requesting the medication for cluster headaches and the requested medication is not sumatriptan injection, sumatriptan nasal spray, or zolmitriptan nasal spray. [Short Description: No approvable diagnosis]
6.	Deny RPh Note: For the denial verbiage, only include the drug the PA is for. Remove all the other drugs from the verbiage.	Approve, 12 months, See Post Limit Quantity Chart	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover an amount for treating eight headaches per month at a maximum daily dose up to: - 18 tablets/month of Amerge Tablets (naratriptan) - 18 tablets/month of Axert Tablets (almotriptan) - 27 tablets/month of Frova Tablets (frovatriptan) - 18 vials/month of Imitrex single-dose vial (sumatriptan) 6mg/0.5mL - 18 syringe cartridges/month of Imitrex prefilled syringe (sumatriptan) 6mg/0.5mL - 27 syringe cartridges/month of Imitrex prefilled syringe (sumatriptan) 4mg/0.5mL - 18 nasal units/month of Imitrex Nasal Spray (sumatriptan) 20mg - 36 nasal units /month of Imitrex Nasal Spray (sumatriptan) 5mg

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- 18 tablets/month of Imitrex Tablets (sumatriptan)
- 27 tablets/month of Maxalt/Maxalt-MLT Tablets (rizatriptan)
- 32 nosepieces (2 kits or 16 pouches)/month of Onzetra Xsail
Nosepiece (sumatriptan)
- 18 tablets/month of Relpax Tablets (eletriptan)
- 18 syringes/month Sumavel DosePro (sumatriptan) 6mg/0.5mL
- 27 syringes /month of Sumavel DosePro (sumatriptan) 4mg/0.5mL
- 24 nasal units/month of Tosymra nasal spray (sumatriptan) 10mg
- 18 tablets/month of Treximet Tablets (sumatriptan) 85mg / 500mg
- 18 tablets/month (27 tablets/3 months) of Treximet Tablets
(sumatriptan) 10mg/60mg
- 36 auto-injectors/month of Zembrace SymTouch (sumatriptan)
- 18 tablets/month of Zomig/Zomig-ZMT Tablets (zolmitriptan)
- 18 nasal units/month of Zomig Nasal Spray (zolmitriptan)
You have been approved for the maximum quantity that your plan
covers for a duration of 12 months. Your request for additional quantities
of the requested drug and strength has been denied.
[Short Description: Over max quantity]

Guidelines for Approval (MMT 903-J)					
	Duration of Approval 12 Months/See Post Limit Quantity Chart				
Set 1 Set 2					
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)		
2	1	5	1		
3	6		2		
4			6		

POST LIMIT QUANTITY

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.

Medication	Strength	Maximum dose per 24 hours	1 Month Limit *	3 Months Limit *
Amerge	1 mg	2 tablets**		
(naratriptan)	2.5 mg	2 tablets 5 mg	18 tablets / 25 days	54 tablets / 75 days
Axert	6.25 mg	2 tablets**		
(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
Imitrex Injection (sumatriptan) single dose vials	6 mg	2 injections 12 mg	18 vials (9mL) / 25 days	55 vials (27.5mL) / 75 days
Imitrex Injection (sumatriptan)	4 mg	3 injections 12 mg	27 syringes (13.5mL) / 25 days	81 syringes (40.5mL) / 75 days
syringes STATdose / Refill	6 mg	2 injections 12 mg	18 syringes (9mL) / 25 days	54 syringes (27mL) / 75 days
Imitrex Nasal Spray (sumatriptan)	5 mg	4 sprays**	36 units / 25 days	108 units / 75 days
	20 mg	2 sprays 40 mg	18 units / 25 days	54 units / 75 days
Imitrex Tablets	25mg, 50mg	2 tablets**	18 tablets / 25 days	54 tablets / 75 days

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(sumatriptan)	100 mg	2 tablets 200 mg		
Maxalt	5 mg	3 tablets**		
Maxalt-MLT (rizatriptan)	10 mg	3 tablets 30 mg	27 tablets / 25 days	81 tablets / 75 days
Onzetra Xsail (sumatriptan)	11mg	4 nosepieces 44mg	32 nosepieces / 25 days (2 kits, 16 pouches)	96 nosepieces / 75 days (6 kits, 48 pouches)
Relpax	20 mg	2 tablets**		
(eletriptan)	40 mg	2 tablets 80 mg	18 tablets / 25 days	54 tablets / 75 days
Sumavel DosePro	4 mg	3 injections 12 mg	27 injections (13.5mL) / 25 days	81 injections (40.5mL) / 75 days
(sumatriptan)	6 mg	2 injections 12 mg	18 injections (9mL) / 25 days	54 injections (27mL) / 75 days
Tosymra (sumatriptan)	10 mg	3 sprays 30 mg	24 units / 25 days	72 units / 75 days
Treximet	10mg/60mg	1 tablet**	18 tablets / 25 days	27 tablets / 75 days
(sumatriptan/naproxe n)	85mg/500mg	1-2 tablets 170mg/1000mg	18 tablets / 25 days	54 tablets / 75 days
Zembrace SymTouch (sumatriptan)	3 mg	4 injections 12mg	36 autoinjectors (18mL) / 25 days	108 autoinjectors (54mL) / 75 days
Zomig Nasal Spray	2.5 mg	2 sprays**		
(zolmitriptan)	5 mg	2 sprays 10 mg	18 units / 25 days	54 units / 75 days
Zomig Tablets Zomig-ZMT (zolmitriptan)	2.5 mg	2 tablets**		
	5 mg	2 tablets 10 mg	18 tablets / 25 days	54 tablets / 75 days

^{*} 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. *The limit criteria apply to both brand and generic, if available.

pharmaceutical manufacturers not affiliated with CVS Caremark.

^{**}Utilize higher strength available.