SmartPA Criteria Proposal

Drug/Drug Class:	Xcopri Clinical Edit
First Implementation Date:	February 18, 2021
Proposed Date:	June 16, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Xcopri® (cenobamate)

Why Issue Selected: Xcopri® (cenobamate) was FDA approved on November 21, 2019, for the treatment of adult patients with partial-onset (or focal) seizures. There are approximately 3 million adults in the United States living with epilepsy and approximately 60% have partial-onset seizures. Despite the availability of many antiepileptic therapies, approximately 20-40% of adults with partial-onset seizures have inadequate control of their seizures, even after treatment with two anti-epileptic drugs. Xcopri was studied only in patients with seizures refractory to between 1-3 anti-epileptic drugs, with 80% of patients on at least 2 concomitant anti-epileptic drugs. Xcopri has an extended titration schedule of up to 12 weeks to reach maintenance therapy due to a risk for Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or Multiorgan Hypersensitivity and is also contraindicated in patients with Familial Short QT syndrome, a very rare genetic disease of the electrical system of the heart. Due to the risk of possible adverse events, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Xcopri therapy.

Program-Specific Information:

Date Range FFS 7-1-2020 to 6-30-2021			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
XCOPRI 50 MG TABLET	45	$45,727.61	$1,016.17
XCOPRI 100 MG TABLET	66	$44,159.97	$669.09
XCOPRI 150 MG TABLET	27	$46,026.00	$1,704.67
XCOPRI 200 MG TABLET	55	$54,651.25	$993.66
XCOPRI 12.5-25 MG TITRATION PACK	38	$3,602.06	$94.79
XCOPRI 50-100 MG TITRATION PACK	16	$12,225.85	$764.11
XCOPRI 150-200 MG TITRATION PACK	5	$4,097.80	$819.56
XCOPRI 250 MG DAILY DOSE PACK	1	$1,042.03	$1042.03
XCOPRI 350 MG DAILY DOSE PACK	0	-	-

Type of Criteria:
☒ **Increased risk of ADE** ☐ **Preferred Drug List**
☒ **Appropriate Indications** ☒ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Xcopri® (cenobamate)
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

Initial Therapy:

- Participant is aged 18 years or older **AND**
- Documented diagnosis of partial-onset or focal seizures **AND**
- Documented therapeutic trial with at least 2 other antiepileptic agents (defined as 30 days) **AND**
- Documentation of current baseline seizure frequency and duration **AND**
- Documentation of current electrocardiogram (to rule out the presence of short QT syndrome) prior to initiation of therapy **AND**
- Prescriber attests that therapy will be initiated by following the recommended 12 week tapering protocol with monitoring for signs and symptoms of DRESS or Multiorgan Hypersensitivity
- Daily dosages above 200mg/day require Clinical Consultant Review

Continuation of Therapy:

- Initial approval is for 6 months, renewal of prior authorization may be given for up to 12 months following documentation of the following:
  - Documentation of therapy meeting the goals of therapy **AND**
  - Documentation of reduced seizure burden or improvement in quality of life using a validated scale for the disease state

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Documented diagnosis of end-stage renal disease with concurrent dialysis
- Documented diagnosis of severe hepatic impairment (Child-Pugh C)

Required Documentation

Laboratory Results:		Progress Notes:	**X**
MedWatch Form:		Other:	**X**

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

6 months

References

- XCOPRI (cenobamate tablets), [package insert]. Paramus, NJ: SK Life Science, Inc.; April 2021.

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- Hoffman, M. Cenobamate Reduces Focal-Onset Seizures in Epilepsy. Cenobamate Reduces Focal-Onset Seizures in Epilepsy (neurologylive.com)November 18, 2019.
- Terry, M. FDA Greenlights SK Biopharma's Xcopri for Partial-Onset Seizures. FDA Greenlights SK Biopharma's Xcopri for Partial-Onset Seizures | BioSpace. November 22, 2019.
- SK Biopharmaceuticals and SK Life Science. FDA Approves XCOPRI® (cenobamate tablets), an Anti-Epileptic Drug (AED) from SK Biopharmaceuticals, Co., Ltd., and U.S. Subsidiary SK Life Science, Inc. FDA Approves XCOPRI® (cenobamate tablets), an Anti-Epileptic Drug (AED) from SK (multivu.com). November 21, 2019.
- Tong, A. New epilepsy company on the block wins FDA approval for made-in-Korea drug to treat focal seizures. New epilepsy company on the block wins FDA approval for made-in-Korea drug to treat focal seizures – Endpoints News (endpts.com). November 22, 2019.
- Tian N, Boring M, Kobau R, Zack MM, Croft JB. Active Epilepsy and Seizure Control in Adults — United States, 2013 and 2015. MMWR Morb Mortal Wkly Rep 2018;67:437–442. Active Epilepsy and Seizure Control in Adults — United States, 2013 and 2015 | MMWR (cdc.gov)
- IPD Analytics. New Drug Review: Xcopri (cenobamate). December 2019.
- IPD Analytics. CNS: Epilepsy/Seizure Disorder. Accessed May 19, 2022.