PRIOR AUTHORIZATION CRITERIA

CLASS	**SELECT MEDICAL DEVICES**
PRODUCT NAME (brand/generic)	**SELECT MEDICAL DEVICES RX ONLY [Use RxClaim List ID CMKJMED002 for target list]**

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref # 2363-A***

COVERAGE CRITERIA

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

- The requested product is being used according to the manufacturer's indication
  AND
- The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to all available FDA-approved drugs and over-the-counter (OTC) products for their medical condition

RATIONALE

The intent of the criteria is to ensure that patients follow selection elements noted in labeling in order to decrease the potential for inappropriate utilization and to confirm the appropriate coverage of select medical devices. A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or
- intended to affect the structure or any function of the body,

and which does not achieve any of its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.[1]

This policy is intended to ensure that select medical devices are utilized in accordance with indications or uses within the manufacturer's guidelines and to foster cost-effective, first-line use of available FDA-approved medications and over-the-counter (OTC) products.

In addition, if the patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to all available FDA-approved drugs and over-the-counter (OTC) products for the patient's medical condition, the prior authorization will be approved. If criteria for coverage are met, the requested medical device will be approved for 3 months.

REFERENCES

1. Medical Devices. Available at: https://www.fda.gov/medical-devices. Accessed September 2021.

Written by:	UM Development (JK/TM/KC)
Date Written:	02/2018
Revised:	(KC) 03/2019 (no clinical changes), 10/2020 (no clinical changes), (TM) 08/2021 (no clinical changes)
Reviewed:	Medical Affairs (SD) 05/2018; (AN) 05/2019; (CHART) 10/29/20, 09/30/2021 MD Committee/P&T committee 05/2018, 05/2019, 12/2019, 10/2020, 11/2021

CRITERIA FOR APPROVAL

1	Is the requested product being used according to the manufacturer's indication? [If no, then no further questions.]	Yes	No
2	Has the patient experienced an inadequate treatment response, intolerance, or does the patient have a contraindication to ALL available FDA-approved drugs and over-the counter (OTC) products for their medical condition?	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this product when used for the manufacturer's indication. Your request has been denied based on the information we have. [Short Description: No approvable use]
2.	Approve, 3 months	Deny	You do not meet the requirements of your plan. Your plan covers this product when you meet these conditions: - You have tried all available FDA-approved drugs for your medical condition and they either did not work for you or you cannot use them - You have tried all available over-the-counter (OTC) products for your medical condition and they either did not work for you or you cannot use them Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance or contraindication to FDA-approved drugs and OTC products]