

PART B STEP THERAPY CRITERIA FOR APPROVAL

Herceptin, Herceptin Hylecta, Herzuma, Ontruzant, and Trazimera will be approved when ALL of the following are met:

1. The requested medication is being used for ONE of the following:
 - A. An FDA approved indication
OR
 - B. An indication in CMS approved compendia
- AND**
2. ONE of the following:
 - A. Information has been provided that indicates the patient has been treated with the requested medication in the past 365 days
OR
 - B. There is documentation that the patient has had an ineffective treatment response to the active ingredient(s) of ALL preferred medication(s)
OR
 - C. The patient has a documented intolerance, hypersensitivity, or FDA labeled contraindication to the active ingredient(s) of ALL preferred medication(s)
OR
 - D. The prescriber has submitted documentation indicating ALL preferred medication(s) are likely to be ineffective or are likely to cause an adverse reaction or other harm to the patient
OR
 - E. BOTH of the following:
 - i. NCCN does NOT specify the preferred medication(s) as a preferred regimen for the requested indication
AND
 - ii. NCCN specifies the requested medication as a preferred regimen for the requested indication

Length of Approval: up to 12 months

See table of preferred medications on next page

NOTES:

- Prerequisite medications may require prior review under Medicare Part D or Medicare Part B. Medicare Part D prerequisites will not be required for Medical Only members.
- Length of approval may be shorter due to provider network participation status.
- Coverage of one Medicare Part B Step Therapy medication could equate to multiple medication authorizations when they share the same Medicare Part B Step Therapy criteria.
- LCD/NCD criteria review completed, if applicable, in addition to the Plan's Medicare Part B Step Therapy criteria.

Targeted Part B Medication	Preferred Medications* †
Herceptin (trastuzumab)	Kanjinti (trastuzumab-anns) and Ogivri (trastuzumab-dkst)
Herceptin Hylecta (trastuzumab and hyaluronidase)	Kanjinti (trastuzumab-anns) and Ogivri (trastuzumab-dkst)
Herzuma (trastuzumab-pkrb)	Kanjinti (trastuzumab-anns) and Ogivri (trastuzumab-dkst)
Ontruzant (trastuzumab-dttb)	Kanjinti (trastuzumab-anns) and Ogivri (trastuzumab-dkst)
Trazimera (trastuzumab-qyyp)	Kanjinti (trastuzumab-anns) and Ogivri (trastuzumab-dkst)

*Preferred medications may vary based upon indication

†Preferred medications require prior authorization under the member's medical (Part B) benefit