| Reference number(s) |
|---|
| 4668-D |

**This document applies to the following:**

| Formulary | Applies |
|---|---|
| Standard Control (SF) | ☑ |
| Standard Control – Choice (SCCF) | ☑ |
| Preferred Drug Plan Design (PDPD) | ☐ |
| Advanced Control Specialty (ACSF) | ☑ |
| Advanced Control Specialty – Choice (ACSCF) | ☑ |
| Managed Medicaid Template (MMT) | ☐ |
| Marketplace (MF) | ☐ |
| Aetna Small Group Affordable Care Act (SG ACA)<br>Aetna Health Exchange (AHE) | ☐ |
| Aetna Individual Lives (IVL) | ☐ |
| Value (VF) | ☑ |

| Formulary | Applies |
|---|---|
| New to Market (NTM) | ☐ |
| Standard Formulary Chart (SFC) | ☑ |
| Basic Control Chart Preferred Drug Plan Design (BCC PDPD) | ☐ |
| Advanced Control Specialty Formulary Chart (ACSFC) | ☑ |
| Value Formulary Chart (VFC) | ☑ |
| Medical Benefit | ☑ |
| Medical Benefit: Advanced Biosimilars First | ☐ |
| Medical Benefit: Managed Medicaid (MMMB) | ☐ |
| Medicare Part B | ☐ |
| Medicare Part B: Advanced Biosimilars First | ☐ |

# Exceptions Criteria
# Trastuzumab Products

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Value Formulary (VF), Advanced Control Specialty Formulary Chart (ACSFC), Standard Control Formulary Chart (SFC), Value Formulary Chart (VFC), and Medical Benefit.

## Plan Design Summary

This program applies to the trastuzumab products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

## Table. Trastuzumab Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

| | **Products** |
| --- | --- |
| **Preferred** | • Kanjinti (trastuzumab-anns)<br>• Trazimera (trastuzumab-qyyp) |
| **Target** | • Herceptin (trastuzumab)<br>• Herceptin Hylecta (trastuzumab and hyaluronidase-oysk)<br>• Herzuma (trastuzumab-pkrb)<br>• Ogivri (trastuzumab-dkst)<br>• Ontruzant (trastuzumab-dttb) |

# Exception Criteria

Coverage for a targeted product is provided when the member has had a documented intolerable adverse event to both of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

# References

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
2. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
3. Herzuma [package insert]. Incheon, Republic of Korea: Celltrion, Inc; May 2019.
4. Kanjinti [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2022.
5. Trazimera [package insert]. Cork, Ireland: Pfizer Ireland Pharmaceuticals; November 2020.
6. Ogivri [package insert]. Steinhausen, Switzerland: Mylan GmbH; July 2023.
7. Ontruzant [package insert]. Whitehouse Station, NJ: Merk Sharp & Dohme Corp.; June 2021.