

This document applies to the following:

| Formulary | Applies |
|--|-------------------------------------|
| Standard Control (SF) | <input checked="" type="checkbox"/> |
| Standard Control – Choice (SCCF) | <input checked="" type="checkbox"/> |
| Preferred Drug Plan Design (PDPD) | <input type="checkbox"/> |
| Advanced Control Specialty (ACSF) | <input checked="" type="checkbox"/> |
| Advanced Control Specialty – Choice (ACSCF) | <input checked="" type="checkbox"/> |
| Managed Medicaid Template (MMT) | <input checked="" type="checkbox"/> |
| Marketplace (MF) | <input checked="" type="checkbox"/> |
| Aetna Small Group Affordable Care Act (SG ACA) | <input type="checkbox"/> |
| Aetna Health Exchange (AHE) | <input type="checkbox"/> |
| Aetna Individual Lives (IVL) | <input type="checkbox"/> |
| Value (VF) | <input checked="" type="checkbox"/> |
| New to Market (NTM) | <input type="checkbox"/> |

| Formulary | Applies |
|---|-------------------------------------|
| Standard Formulary Chart (SFC) | <input checked="" type="checkbox"/> |
| Basic Control Chart Preferred Drug Plan Design (BCC PDPD) | <input type="checkbox"/> |
| Advanced Control Specialty Formulary Chart (ACSFC) | <input checked="" type="checkbox"/> |
| Value Formulary Chart (VFC) | <input checked="" type="checkbox"/> |
| Medical Benefit | <input type="checkbox"/> |
| Medical Benefit: Advanced Biosimilars First | <input type="checkbox"/> |
| Combined Benefit Medical Specialty (CBMS) | <input type="checkbox"/> |
| Medical Benefit: Managed Medicaid (MMMB) | <input type="checkbox"/> |
| Medicare Part B | <input type="checkbox"/> |
| Medicare Part B: Advanced Biosimilars First | <input type="checkbox"/> |

Exceptions Criteria

Primary Biliary Cholangitis (PBC)

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), Managed Medicaid Template (MMT), Marketplace Formulary (MF), Standard Formulary Chart (SFC), Advanced Control Specialty Formulary Chart (ACSFC), and Value Formulary Chart (VFC).

Plan Design Summary

This program applies to the primary biliary cholangitis (PBC) products specified in this document. Coverage for the 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. Primary Biliary Cholangitis Products

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

| | Product(s) |
|-----------|---|
| Preferred | <ul style="list-style-type: none"> Iqirvo (elafibranor) |
| Target | <ul style="list-style-type: none"> Livdelzi (seladelpar) Ocaliva (obeticholic acid) |

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for Livdelzi or Ocaliva is provided when the member has a documented inadequate response or intolerable adverse event with the preferred product Iqirvo.

References

1. Iqirvo [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2024.
2. Livdelzi [package insert]. Foster City, CA: Gilead Sciences, Inc.; August 2024.
3. Ocaliva [package insert]. Morristown, NJ: Intercept Pharmaceuticals, Inc.; May 2022.