PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Zolinza Prior Authorization Policy
- Zolinza® (vorinostat capsules – Merck)

REVIEW DATE: 07/02/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Zolinza, a histone deacetylase inhibitor, is indicated for the treatment of cutaneous manifestations of **cutaneous T-cell lymphoma** in patients who have progressive, persistent or recurrent disease on or following two systemic therapies.[1]

Guidelines

Zolinza is discussed in guidelines from The National Comprehensive Cancer Network (NCCN):

- **Hodgkin lymphoma:** NCCN guidelines (version 2.2025 – January 30, 2025) recommend Zolinza for subsequent therapy for disease refractory to at least 3 prior lines of therapy in combination with Keytruda (pembrolizumab) (category 2A).[4]
- P**rimary cutaneous lymphomas:** NCCM guidelines (version 3.2025 – June 10, 2025) recommend Zolinza as a systemic therapy for mycosis fungoides/Sezary syndrome.[2,3] Zolinza can be used for primary treatment or for relapsed, persistent, or refractory disease.

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Zolinza. All approvals are provided for the duration noted below.

- **Zolinza® (vorinostat capsules – Merck)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome.** Approve for 1 year.

Other Uses with Supportive Evidence

2. **Classic Hodgkin Lymphoma.** Approve for 1 year if patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least three systemic regimens; AND
   Note: Examples of systemic regimens are ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine) + rituximab, CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab, CVbP (cyclophosphamide, vinblastine, prednisolone) + rituximab, Adcetris (brentuximab vedotin intravenous infusion) + AVD (doxorubicin, vinblastine, dacarbazine).
   C) The medication is used in combination with Keytruda (pembrolizumab intravenous infusion).

CONDITIONS NOT COVERED

- **Zolinza® (vorinostat capsules – Merck)**

is(are) considered not medically necessary for ANY other use(s).

REFERENCES

1. Zolinza® capsules [prescribing information]. Whitehouse Station, NJ: Merck & Co.; July 2022.
2. The NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (version 3.2025 – June 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 17, 2025.
3. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 17, 2025. Search term: vorinostat.
4. The NCCN Hodgkin Lymphoma Clinical Practice Guidelines in Oncology (version 2.2025 – January 30, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 17, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/02/2023

Annual Revision	No criteria changes.	07/31/2024
Annual Revision	**Classic Hodgkin Lymphoma:** Added as a new condition for approval under Other Uses with Supportive Evidence section.	07/02/2025