PRIOR AUTHORIZATION POLICY

POLICY: Sickle Cell Disease – Oxbryta Prior Authorization Policy
- Oxbryta® (voxelotor tablets, tablets for oral suspension – Global Blood Therapeutics/Pfizer)

REVIEW DATE: 10/01/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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

Oxbryta, a hemoglobin S (or sickle hemoglobin) polymerization inhibitor, is indicated for the treatment of **sickle cell disease** in patients ≥ 4 years of age.[1] This indication is approved under accelerated approval based on increase in hemoglobin. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Oxbryta Withdrawal

On September 25, 2024, Pfizer announced that it is voluntarily withdrawing all lots of Oxbryta for the treatment of sickle cell disease, in all markets where it is approved.[2] Furthermore, all active clinical trials and expanded access programs worldwide are also being discontinued. Pfizer's decision is based on totality of clinical data that shows the overall benefit of Oxbryta no longer outweighs the risk in patients with sickle cell disease. Pfizer notes that physicians should continue to monitor patients for adverse events after their treatment with Oxbryta is discontinued and ensure appropriate follow-up as needed.[3] Complications when treatment is interrupted abruptly cannot be excluded and neither efficacy nor a dose for gradual discontinuation have been established.

POLICY STATEMENT

Pfizer is voluntarily withdrawing all lots of Oxbryta for the treatment of sickle cell disease, in all markets where it is approved. Coverage of Oxbryta is not approved.

CONDITIONS NOT COVERED

Oxbryta® (voxelotor tablets, tablets for oral suspension – Global Blood Therapeutics/Pfizer) is(are) considered experimental, investigational or unproven for ANY use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Sickle Cell Disease.** On September 25, 2024, Pfizer announced that it is voluntarily withdrawing all lots of Oxbryta for the treatment of sickle cell disease, in all markets where it is approved.[2] Coverage of Oxbryta will not be approved.

REFERENCES

1. Oxbryta™ tablets and tablets for oral suspension [prescribing information]. San Francisco, CA: Global Blood Therapeutics; October 2022.
2. Pfizer voluntarily withdraws all lots of sickle cell disease treatment Oxbryta (voxelotor) from worldwide markets. Released on September 25 2024. Available at: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-voluntarily-withdraws-all-lots-sickle-cell-disease. Accessed on September 30, 2024.
3. Pfizer – Dear Healthcare Provider letter for Oxbryta. Released on September 26, 2024. Available at: https://www.pfizermedicalinformation.com/sites/default/files/resource/UPDATED_FINAL_DHCP_Letter_FDA_092624.pdf. Accessed on September 30, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/03/2024
Early Annual Revision	Pfizer is voluntarily withdrawing Oxbryta from the market. Coverage of Oxbryta will not be approved.	10/01/2024