

## PRIOR AUTHORIZATION POLICY

**POLICY:** Sickie Cell Disease – Oxbryta Prior Authorization Policy

- Oxbryta® (voxelotor tablets, tablets for oral suspension – Global Blood Therapeutics/Pfizer)

**REVIEW DATE:** 10/01/2024

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### OVERVIEW

Oxbryta, a hemoglobin S (or sickle hemoglobin) polymerization inhibitor, is indicated for the treatment of **sickle cell disease** in patients  $\geq 4$  years of age.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

None.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Oxbryta is not recommended in the following situations:

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.<sup>2</sup> Coverage of Oxbryta will not be approved.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

10/01/2024

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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](https://www.pfizermedicalinformation.com/sites/default/files/resource/UPDATED_FINAL_DHCP_Letter_FDA_092624.pdf). Accessed on September 30, 2024.