

Polivy and Use of Methotrexate for Central Nervous System Prophylaxis in Patients with Previously Untreated Diffuse Large B-cell Lymphoma

This article responds to your request for information on the use of methotrexate for CNS prophylaxis in patients with previously untreated DLBCL receiving treatment with Polivy® (polatuzumab vedotin). This response was developed according to the principles of evidence-based medicine and contains data from clinical trials.

Consult your local prescribing information for product use instructions. Any actions beyond the approved label information are the responsibility of the user.

In brief

- There is no recommendation on treatment for CNS prophylaxis for patients on Polivy.
- In the Phase 3 POLARIX study patients in both arms could receive IT CNS prophylaxis, but high-dose IV MTX was not allowed and was considered a new anti-lymphoma therapy.
- There is no real world evidence of use of high-dose MTX for CNS prophylaxis in patients receiving Polivy.

Abbreviations

CNS=central nervous system

DLBCL=diffuse large B-cell lymphomaIT=intrathecal

IV=intravenous

MTX=methotrexate

R-CHP=rituximab, cyclophosphamide, doxorubicin, and prednisone

R-CHOP = rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone

CNS prophylaxis for patients on Polivy

There is no recommendation on treatment for CNS prophylaxis for patients on Polivy.¹

CNS prophylaxis in the POLARIX study in patients with previously untreated DLBCL

The Phase 3 POLARIX study compared Polivy-R-CHP versus R-CHOP in patients with previously untreated DLBCL.²

In this study, patients in both arms could receive IT CNS prophylaxis, per institutional practice. High-dose IV MTX (e.g. 1 g/m² per cycle) was not allowed and was considered a new anti-lymphoma therapy.³

Patients who received CNS prophylaxis

In the Polivy-R-CHP group, 72 patients (16.4%) and in the R-CHOP group 86 patients (19.6%) received CNS prophylaxis.⁴ CNS prophylaxis included any IT administration of MTX, cytarabine, or corticosteroid.⁴

Some patients in the Polivy-R-CHP arm received MTX as a concomitant treatment during the study treatment period or during the follow-up period. It was not specified how many of these patients received IT MTX for CNS prophylaxis.⁵

Case reports of high-dose MTX for CNS prophylaxis

There is no real world evidence of use of high-dose MTX for CNS prophylaxis in patients receiving Polivy.

References

1. Roche Internal Regulatory Document (Accessed on July 25, 2023).
2. Tilly H, Morschhauser F, Sehn L, et al. Polatuzumab Vedotin in Previously Untreated Diffuse Large B-Cell Lymphoma. *N Engl J Med* 2022;386:351-363. <https://www.ncbi.nlm.nih.gov/pubmed/34904799>
3. Protocol for Polatuzumab Vedotin in Previously Untreated Diffuse Large B-Cell Lymphoma. Available at https://www.nejm.org/doi/suppl/10.1056/NEJMoa2115304/suppl_file/nejmoa2115304_protocol.pdf. Accessed on July 25, 2023.
4. The New England Journal of Medicine. Table S2 in Supplementary Appendix of Polatuzumab Vedotin in Previously Untreated Diffuse Large B-Cell Lymphoma. January 27, 2023. Available at https://www.nejm.org/doi/suppl/10.1056/NEJMoa2115304/suppl_file/nejmoa2115304_appendix.pdf. Accessed on July 25, 2023.
5. Roche Internal Clinical Study Report (Accessed on July 25, 2023).