

Guidelines for Determining Lines of Therapy in DLBCL

A Line of Therapy (LOT) is defined as a distinct course of treatments administered with the intention to control or eradicate disease, starting on the first day of drug administration and continuing until treatment discontinuation or initiation of a new therapy.

Criteria defining a new Line of Therapy

- Progressive Disease (PD)/Stable Disease (SD)/Partial Response (PR) **define a new line of therapy.**
- Switch in mechanism of action or addition of a drug with a new mechanism of action even in the absence of PD/SD/PR response.
- Gap/break of > 180 days even in the absence of PD/SD/PR response.
- Clinical trial (i.e., investigational) drugs should be considered a separate line of therapy (applicable only to LOTs following the index LOT, as patients participating in a clinical trial in the index LOT are excluded).

Situations that do not define a new Line of Therapy

- Changes in route of administration, dosage or cycle interval do not define a new line of therapy.
- Supportive therapy and radiotherapy alone are not a line of therapy. Radiotherapy will be documented separately.
- Maintenance therapy or agents used to reduce the toxic effect of steroids (e.g. Prednisone) alone is grouped with the previous line.
- Cell therapies:
 - Stem cell transplantations are grouped with any preceding salvage, conditioning, and/or consolidation therapy as well as following maintenance therapy, if any.
 - CAR-T is grouped with preceding lymphodepletion and bridging therapies.