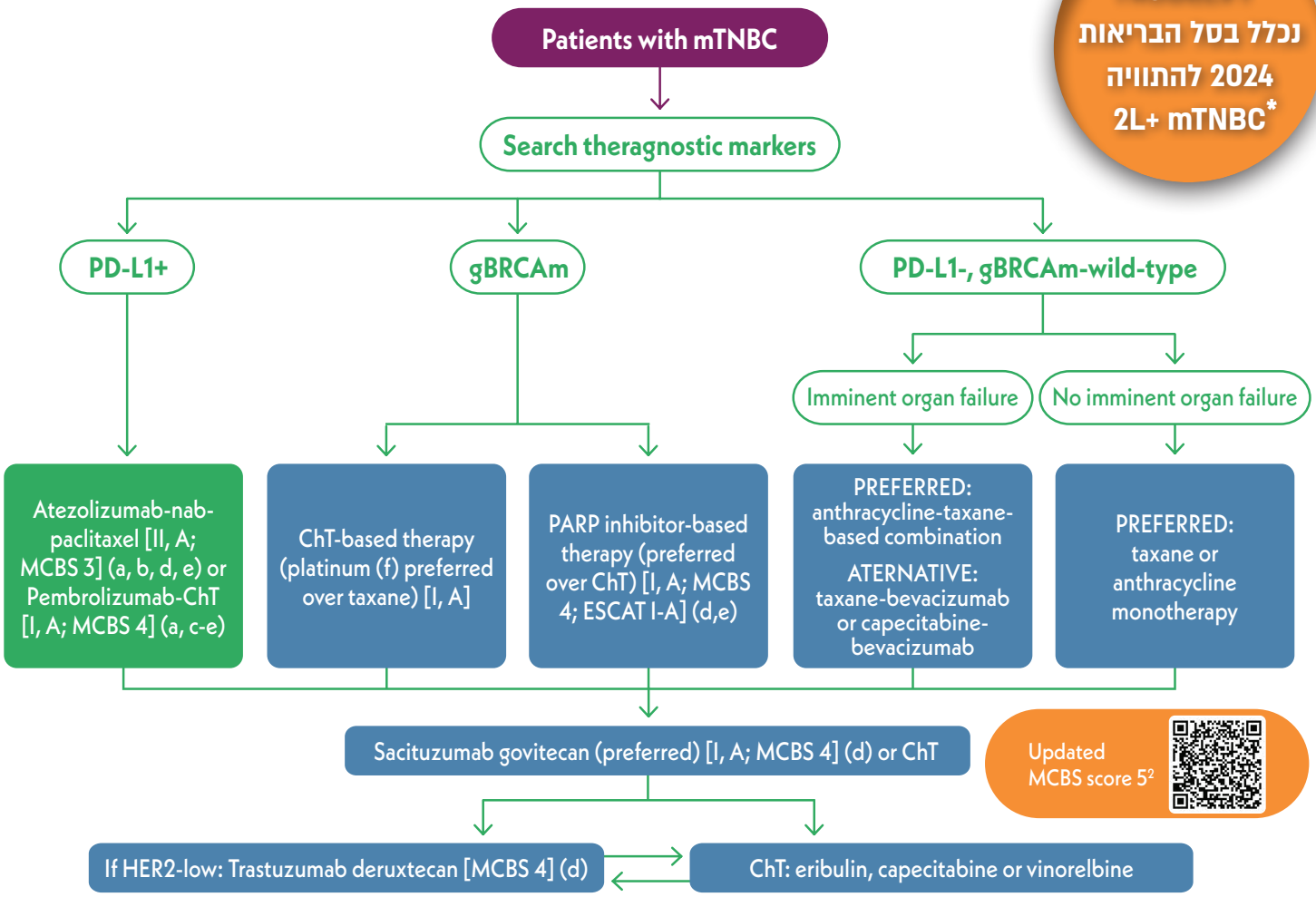
ESMO guidelines recommend TRODELVY® as the preferred 2nd line treatment for all mTNBC patients with an updated MCBS score 5*,1,2

GILEAD | Oncology

TRODELVY® נכלל בסל הבריאות להתוויה 2024 2L+ mTNBC*



Purple: general categories or stratification; green: combination of treatments or other systemic treatments; white: other aspects of management; blue: systemic anticancer therapy.

(a) May be considered as monotherapy in further lines in case of high PD-L1 positivity and no previous exposure to ICI. (b) EMA approved, not FDA approved. (c) ChT physician's choice of nab-paclitaxel, paclitaxel or gemcitabine/carboplatin. (d) ESMO-MCBS v1.1 (Cherny, 2017) was used to calculate scores for new therapies/indications approved by the EMA or FDA. The scores have been calculated by the ESMO-MCBS Working Group and validated by the ESMO Guidelines Committee (https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-evaluation-forms). (e) ESCAT scores apply to genomic alterations only. These scores have been defined by the guideline authors and validated by the ESMO Translational Research and Precision Medicine Working Group. (Mateo, 2018) (f) If not used previously

TNBC definition and diagnosis

ASCO/CAP guidelines define triple-negative breast cancer as HR-, as well as HER2-negative expression, including IHC0, IHC1+, or IHC2+ with negative ISH[3]

Triple- Negative Breast Cancer (TNBC)

HR - +

HER2- status

IHC 0	OR	IHC 1+	OR	IHC 2+/ ISH-	
No staining observed OR incomplete membrane staining that is faint or barely perceptible and within ≤ 10% of the tumor cells		Incomplete membrane staining that is faint or barely perceptible and within > 10% of the tumor cells		Weak to moderate complete membrane staining observed in >10% of tumor cells	HER2/CEP17 ratio < 2.0 and average HER2 copy number ≥ 4.0 and < 6.0 signals/cell

HER2 low

*בהתאם להתוויה המלאה המאושרת ע"י משרד הבריאות בישראל

GILEAD | Oncology

TRODELVY®
sacituzumab govitecan
200 mg powder for concentrate for solution for infusion

TRODELVY® נכלל בסל הבריאות להתוויה 2024 2L+ mTNBC*

TRODELVY® indication in mTNBC[4]

Indication for Patients with disease progression to mTNBC after receiving Neoadjuvant/Adjuvant systemic treatment:

Treatment in early stage ▶ **Treatment in mTNBC**

received
Neoadjuvant or adjuvant
Systemic treatment

received
1L
Systemic treatment

2L TRODELVY®

Indication for Patients with De-Novo mTNBC

Trodelvy can be prescribed after 2 systemic treatment lines

Trodelvy® (sacituzumab govitecan 200 mg) Powder for concentrate for solution for infusion.

Indication in mTNBC: Trodelvy as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic triple-negative breast cancer **(mTNBC)** who have received two or more prior systemic therapies, including at least one of them for advanced disease.

TRODELVY® מותווה ונכלל בסל הבריאות עבור גידולי mTNBC המבטאים כל רמה של HER2- (negative),
כלומר, IHC 0 וגם HER2 low (IHC1+, IHC2+/ISH-).

Trodelvy® (sacituzumab govitecan 200 mg) Powder for concentrate for solution for infusion.
INDICATION: Trodelvy as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, including at least one of them for advanced disease.

Trodelvy is indicated for the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

*בהתאם להתוויה המלאה המאושרת ע"י משרד הבריאות בישראל

IL-TRO-0254IL-TRO-0277

Adverse events should be reported to the Ministry of Health (www.health.gov.il or by clicking on the link: https://sideeffects.health.gov.il). Additionally, adverse events can be reported directly to the registration holder via email: Safety_FC@gilead.com.

References:

1. ESMO Metastatic Breast Cancer Living Guidelines, v1.1 May 2023; original Clinical Practice Guideline Ann Oncol 2021;32(12): 1475-1495.
2. https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-for-solid-tumours/esmo-mcbs-scorecards/scorecard-271-1
3. https://www.cap.org/protocols-and-guidelines/current-cap-guidelines
4. TRODELVY (sacituzumab govitecan) prescribing information approved by Israeli ministry of health

For further information please refer to approved prescribing information as available at Israeli ministry of health website: