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ADC and AEs

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ADCs IN HER2⁺ METASTATIC BREAST CANCER AND MANAGEMENT OF AEs

Clinical question

How can key adverse events (AEs) associated with next-generation HER2-targeted antibody–drug conjugates (ADCs) be managed?

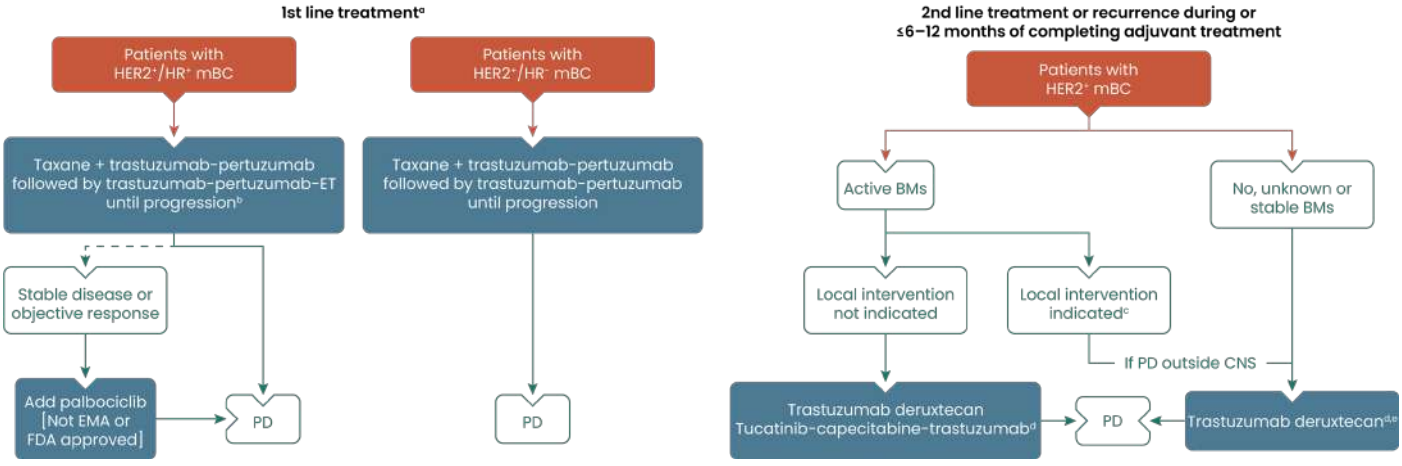
Document purpose

To understand the role of ADCs in treatment of patients with HER2⁺ metastatic breast cancer (mBC); promptly identify and proactively manage the most common AEs linked to next-generation HER2-targeted ADCs; and provide evidence-based consensus strategies for optimal monitoring, dose modifications, and supportive care to optimise patient experience and improve long-term outcomes. For patient-friendly support, a one-page factsheet is included at the end of this document.

Introduction

HER2⁺ tumours are among the most aggressive subtypes of breast cancer and HER2-targeted treatments represent a cornerstone in the standard of care for patients with HER2⁺ mBC. International guidelines (figure 1) recommend a taxane combined with trastuzumab and pertuzumab as standard 1st line therapy for HER2⁺ mBC, regardless of HR status.[1] Importantly, trastuzumab deruxtecan (T-DXd), an ADC, plus pertuzumab has received FDA-approval as a 1st line therapy based on the DESTINY-Breast09 trial,[2] though ESMO/ASCO guidelines have not yet incorporated this update. For HER2⁺ patients with HR⁺ disease, endocrine therapy (ET) may be added to trastuzumab–pertuzumab maintenance after completion of chemotherapy (ChT); patients with metastatic recurrence during or ≤12 months of completing adjuvant trastuzumab–pertuzumab should follow 2nd line therapy recommendation.[1] The recommended 2nd line treatment option is currently T-DXd, an ADC, for patients previously treated with a taxane plus trastuzumab (with or without pertuzumab).[1] Trastuzumab emtansine (T-DM1) is the only other approved ADC for this tumour subtype by the FDA/EMA, and may be used where T-DXd is not available and/or has already been used in prior lines of treatment. 3rd line treatment choice depends on prior therapy, patient characteristics, toxicity profile, and availability.[1]

Figure 1. Clinical practice guidelines for HER2⁺ mBC[1]



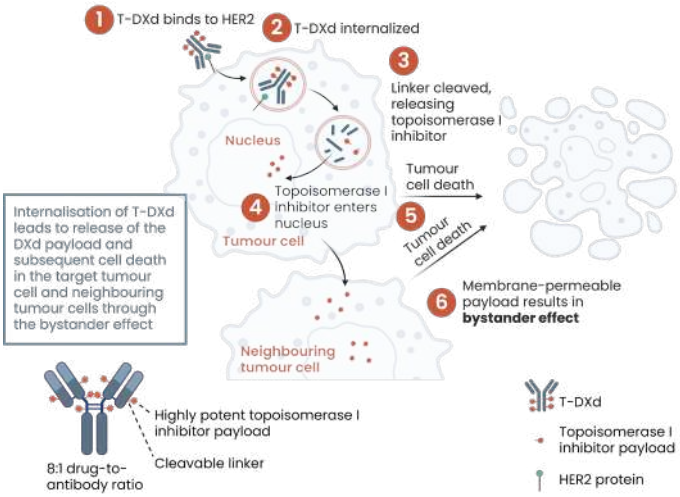
[a] For ERBB2-amplification.
[b] Ovarian function suppression should also be added for pre- and perimenopausal women.
[c] Keep on current systemic therapy unless PD outside CNS.
[d] Not FDA approved for use in 2nd line.
[e] T-DM1 is a 2nd line treatment option after progression on a taxane and trastuzumab in cases where trastuzumab deruxtecan is not available.

T-DXd mechanism of action

T-DXd is an ADC comprising a humanised, anti-HER2 IgG1 monoclonal antibody, covalently linked to a topoisomerase I inhibitor payload, DXd, via a cleavable tetrapeptide-based linker; it has a higher drug-to-antibody ratio (DAR) (8:1) than trastuzumab emtansine (T-DM1, 3.5:1).[3–6]

This high DAR allows delivery of a high concentration of the DXd cytotoxic agent to the target cells enhancing anti-tumour activity.[7] In contrast to T-DM1, T-DXd has a tumour-selective cleavable linker and internalisation of T-DXd leads to release of the DXd payload and subsequent cell death in the target tumour cell as well as neighbouring tumour cells.[7,8] Thus, T-DXd but not T-DM1, shows evidence of a bystander anti-tumour effect (figure 2).[8–12]

Figure 2. Structure and mechanism of action of T-DXd[8,9]



T-DXd clinical trial data

The recommended dosage of T-DXd for HER2⁺ mBC is 5.4 mg/kg given as an IV infusion once every 3 weeks (21-day cycle) until there is evidence of disease progression or unacceptable toxicity.[14] In the pivotal DESTINY-Breast03 study among patients with HER2⁺ mBC previously treated with trastuzumab and a taxane, T-DXd demonstrated superior efficacy over T-DM1 in the long-term with a manageable safety profile (figure 3).[13] In this study, median progression-free survival (mPFS) was 29.0 versus 7.2 months (hazard ratio, 0.30; 95% CI, 0.24–0.38) and 5-year median overall survival (mOS) was 56.4 months with T-DXd and 42.7 months with T-DM1; 26% lower risk of death.[13,15] T-DXd is superior to T-DM1 in reducing the risk of progression or death in patients with HER2⁺ mBC previously treated with trastuzumab and a taxane.[16]

Furthermore, DESTINY-Breast09 demonstrated superior mPFS with T-DXd plus pertuzumab versus standard 1st line therapy (40.7 vs 26.9 months; hazard ratio 0.56 [95% CI: 0.44, 0.71]),[2] supporting FDA approval (figure 4).

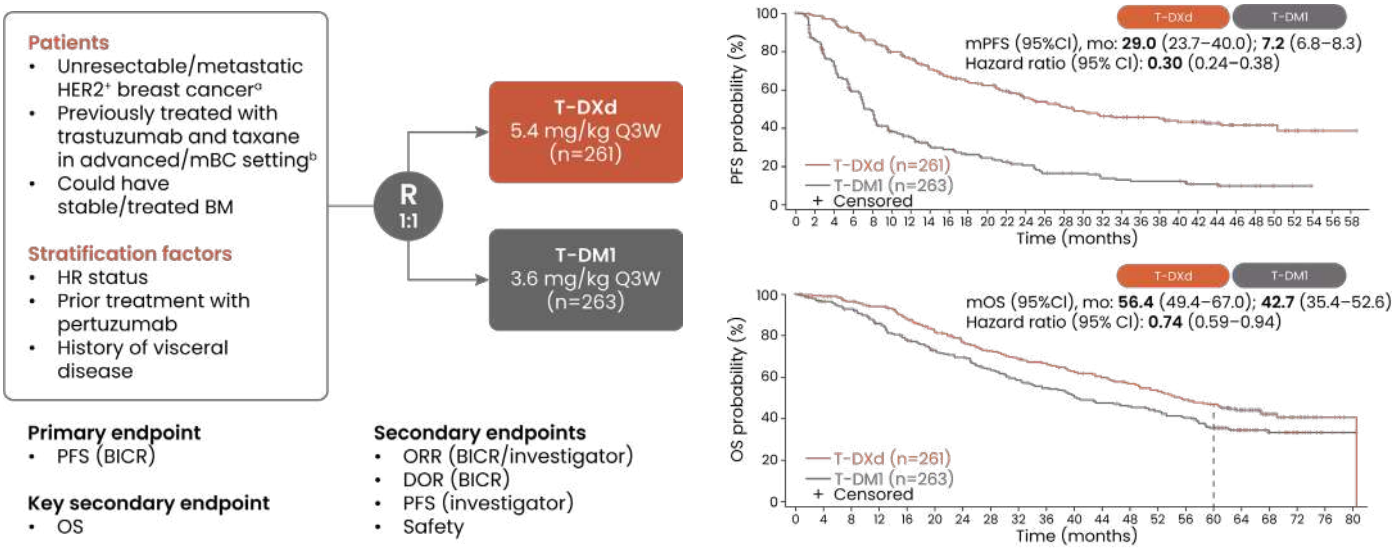
The most common drug-related AEs of any grade (G) with T-DXd monotherapy were nausea (73%), fatigue (45%), and vomiting (44%; Table 1).[13] In DESTINY-Breast03, the incidence of interstitial lung disease (ILD) and pneumonitis was numerically lower than in earlier trials.[16] Long-term follow-up (median 41 months) revealed no new safety signals, supporting the favourable benefit–risk profile of T-DXd.[16] Nevertheless, careful and proactive monitoring of T-DXd-associated AEs remains essential to optimise patient outcomes.

Table 1. Key drug-related AEs in DESTINY-Breast03[13] and DESTINY-Breast09[2]

Adverse event (drug-related)[a]	DESTINY-Breast03 (T-DXd, n=257)	DESTINY-Breast03 (T-DM1, n=261)	DESTINY-Breast09 (T-DXd + pertuzumab, n=381)	DESTINY-Breast09 (THP[b], n=382)
Any AE	98.1%	86.6%	97.9%	96.6%
G≥3 AEs	45.1%	39.8%	54.9%	52.4%
Nausea (any G)	72.8%	27.6%	71.1%	28.8%
Fatigue (any G)	44.7%	29.5%	48.3%	34.6%
Vomiting (any G)	44.0%	5.7%	42.0%	13.4%
Alopecia (any G)	36.2%	2.3%	46.2%	50.0%
Neutropenia (any G)	42.8%	11.1%	48.8%	44.5%
Anaemia (any G)	30.4%	14.2%	35.4%	39.0%
ILD / pneumonitis (any G)	10.5%	1.9%	12.1%	1.0%
G≥3 ILD / pneumonitis	0.8%	0%	0.5%	0%

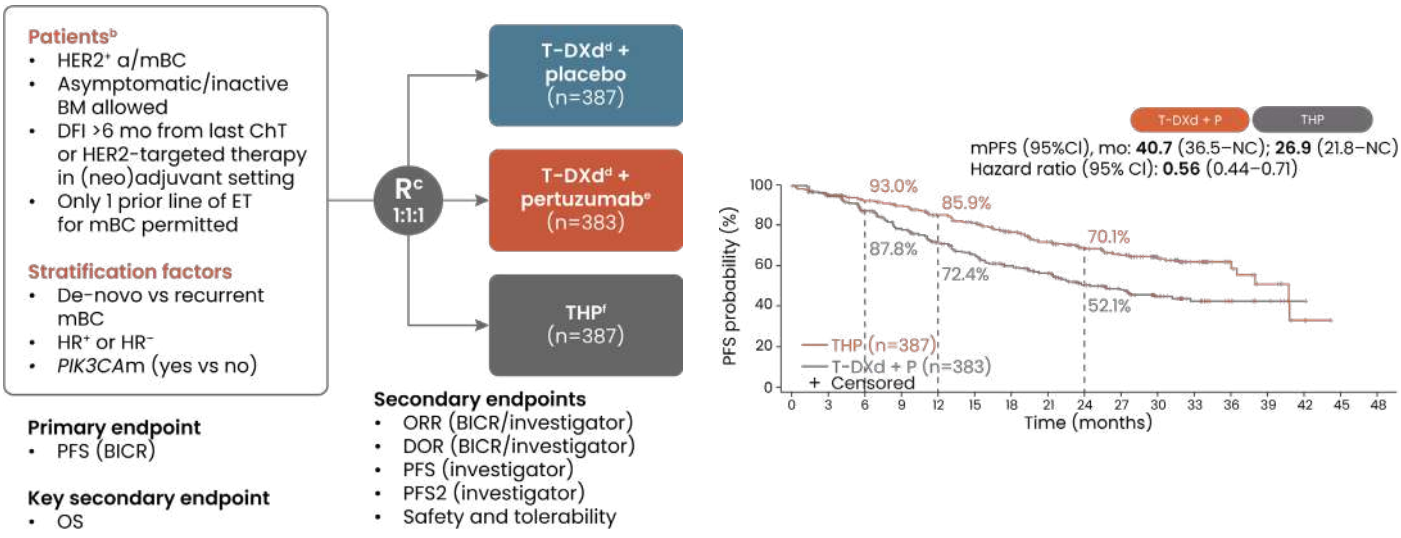
[a] AEs in >30% of patients receiving T-DXd in DESTINY-Breast03 and adjudicated drug-related ILD/pneumonitis.
[b] THP = paclitaxel or docetaxel + trastuzumab + pertuzumab.

Figure 3. DESTINY-Breast03: Study design and efficacy results[13,15]



[a] HER2 IHC3+ or IHC2+/ISH+ based on central confirmation.
[b] Progression during or <6 months after completing adjuvant therapy involving trastuzumab and taxane.

Figure 4. DESTINY-Breast09: Study design[a] and efficacy results[2]



[a] Open-label for THP arm double-blinded for pertuzumab in experimental arms.
[b] Concurrent use of ET (aromatase inhibitor or tamoxifen) was allowed for those with HR+ disease after six cycles of T-DXd or discontinuation of taxane in THP arm.
[c] If T-DXd was discontinued due to AEs (except G ≥2 ILD), patients could switch to trastuzumab (without loading dose).
[d] 5.4 mg/kg Q3W.
[e] 840 mg loading dose, then 420 mg Q3W.
[f] THP = paclitaxel 80 mg/m² QW or 175 mg/m² Q3W, or docetaxel 75 mg/m² Q3W for a minimum of six cycles or until intolerable toxicity + trastuzumab at 8 mg/kg loading dose, then 6 mg/kg Q3W + pertuzumab at 840 mg loading dose.

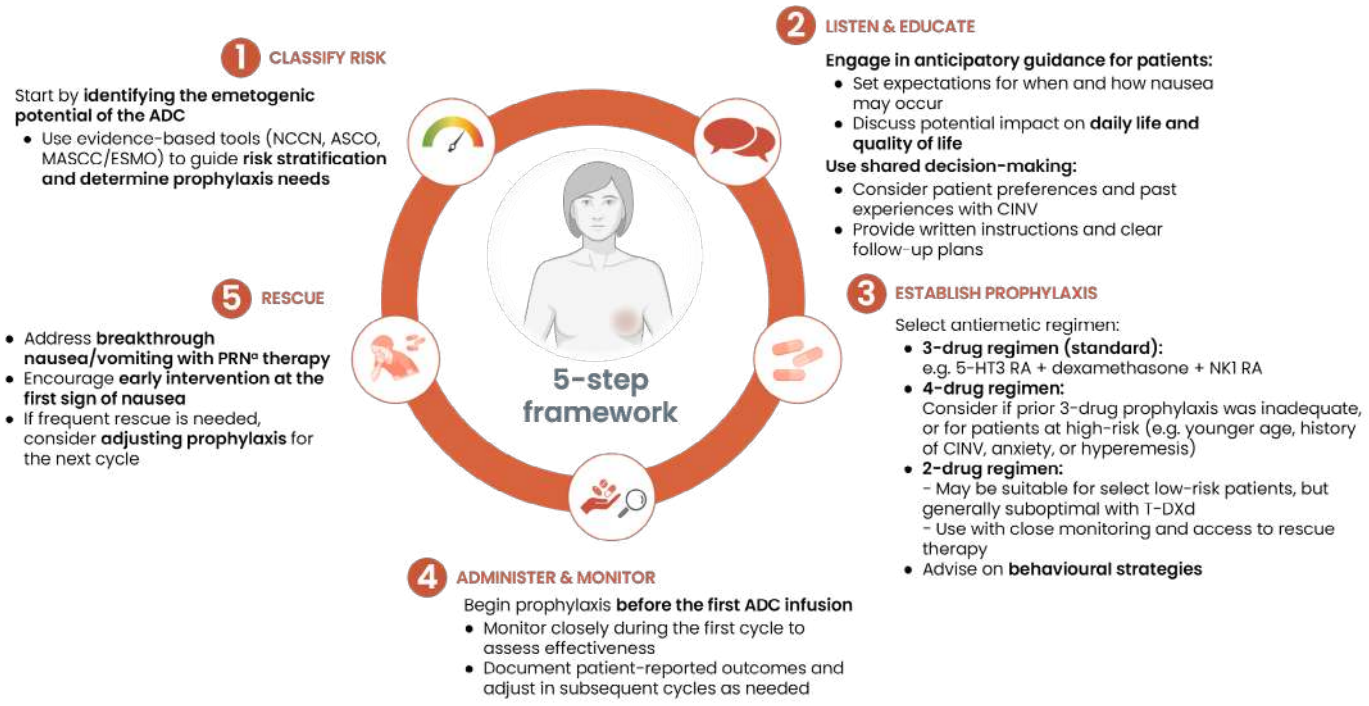
Consensus framework for HCPs managing AEs associated with T-DXd

Nausea and vomiting

Based on expert consensus opinion, a 5-step framework for managing T-DXd–induced nausea and vomiting can be recommended.

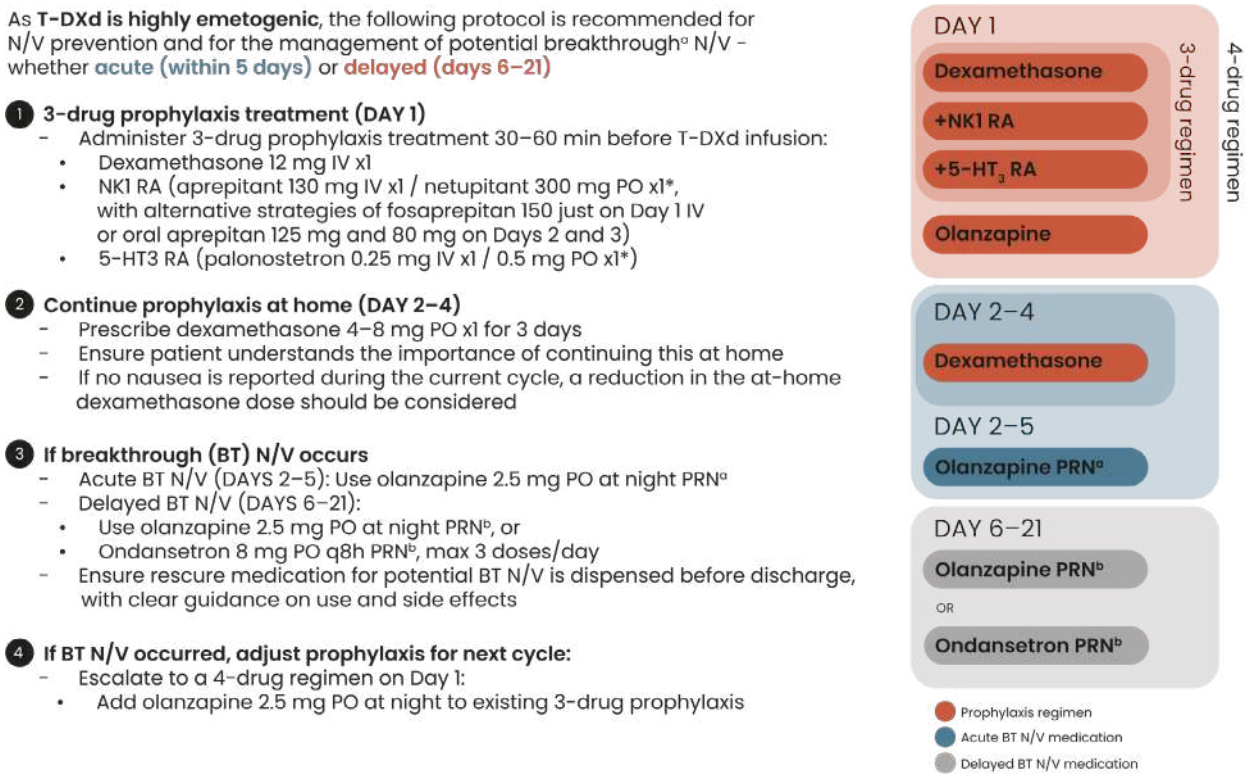
1. Classifying the emetogenic risk of the ADC
2. Shared decision-making, by listening to the patient and providing written instructions on expectations and potential impact on daily life
3. Establishing prophylaxis to manage symptoms before they start or at delayed onset
4. Administering prophylaxis and regular monitoring of the effectiveness of the chosen regimen
5. Initiating rescue interventions and adjusting patient management strategy if needed

Figure 5. 5-step framework for managing T-DXd induced nausea and vomiting



[a] PRN, or pro re nata, therapy refers to medications that are not administered on a fixed schedule but are taken only when necessary, based on the patient's symptoms.

Figure 6. Expert consensus protocol for managing T-DXd-induced nausea and vomiting (N/V)



[a] Breakthrough (BT) N/V refers to N/V that occurs despite appropriate prophylactic treatment.
[b] PRN (pro re nata) refers to medication taken as needed, rather than on a fixed schedule. In this context, it is used when acute (Day 2–5 of the cycle) or delayed (Day 6–21) N/V occur despite appropriate prophylaxis, requiring additional treatment to manage symptoms.
[c] A 4-drug prophylactic regimen including olanzapine is recommended if prior 3-drug prophylaxis was inadequate, or for patients who are at high-risk (e.g. younger age, history of CINV, anxiety, or hyperemesis).
[d] T-DXd is given on Day 1 of a 21-day cycle.

Recommended prophylactic regimen

T-DXd–induced N/V is defined as "acute" if onset is up to five days after the T-DXd infusion; if onset is between days 6 and 21 after the infusion, then it is defined as "delayed". As T-DXd is a highly emetogenic agent, clinical experience and expert consensus suggest a 3-drug prophylactic regimen (dexamethasone + NK1RA + 5-HT3RA) approximately 30–60 minutes before T-DXd infusion on the first day of a 21-day cycle. A 4-drug prophylactic regimen is recommended if 3-drug prophylaxis was inadequate or for patients at high-risk (e.g. younger age, history of chemotherapy-induced nausea and vomiting, anxiety, or hyperemesis). In addition, rescue antiemetic medication should be dispensed before discharge to manage breakthrough N/V across the full 21-day cycle, with clear instructions on use and potential side effects. Olanzapine may be used as needed for acute or delayed breakthrough N/V, with ondansetron as an alternative for delayed nausea (figure 6).

Management of other adverse events

Based on a previously published expert consensus[16] and opinions of the BluePrint Steering Committee, the following strategies can be adopted for managing the other AEs associated with ADCs, such as fatigue (figure 7) and ILD (figure 8).

Fatigue

Education and support should be provided for all patients as routine. Up-front and ongoing education for patients and caregivers on side effects and how to identify and manage them is essential. In addition, suggesting the use of validated digital patient-reported outcome tools (such as mobile apps or secure online platforms) to patients may complement routine clinical assessments by enabling ongoing symptom monitoring between visits and facilitating earlier detection of adverse events, an approach shown to improve symptom control and clinical outcomes.[18]

Screening and regular assessment should be performed throughout the patient journey. HCPs should conduct full clinical and symptom assessments and assess for reversible causes of any symptoms such as pain, depression, insomnia, nutrition, or comorbidities. This will allow HCPs to treat identified causes. In general, specific guidelines for reversible contributors should be followed (e.g. NCCN guidelines[19]) and short-term pharmacological options for metastatic patients should be initiated if required. Patients should be encouraged into physical activity if feasible.

If needed, the HCP can adjust T-DXd dose, which may alleviate fatigue (figure 7). Based on expert clinical experience, no cumulative fatigue has been observed during the treatment course with T-DXd.

Interstitial lung disease

In a pooled analysis of clinical studies, approximately 10–15% of patients receiving T-DXd were reported to develop ILD/pneumonitis, with a median time to onset of 5–6 months, with the majority only experiencing low-grade events (G1/2, 77.4%).[20] In general, the five 'S' rules (screen, scan, synergy, suspend treatment, and steroids) are strategies that can help minimise the risk and impact of T-DXd–related ILD (figure 8).[21] Low-grade ILD can usually be well-managed with a comprehensive multidisciplinary approach of early diagnosis, initiation of steroids, and close monitoring; patient education to recognise symptoms is also important.[22] Permanent discontinuation of T-DXd is recommended for G2–G4 ILD.[21]

Figure 7. Managing T-DXd related fatigue[17]

Screen and assess regularly
- Fatigue is subjective: use validated tools (e.g. Numeric Rating Scale)
- Assess for reversible causes: pain, depression, insomnia, nutrition, comorbidities
- Conduct full clinical and symptom assessment

Treat identified causes
- Follow specific guidelines for reversible contributors (e.g. NCCN guidelines)
- Encourage physical activity if feasible
- Short-term pharmacological options for metastatic patients

Educate and support
- Ongoing education for patients and caregivers is essential
- Reinforce realistic expectations and coping strategies

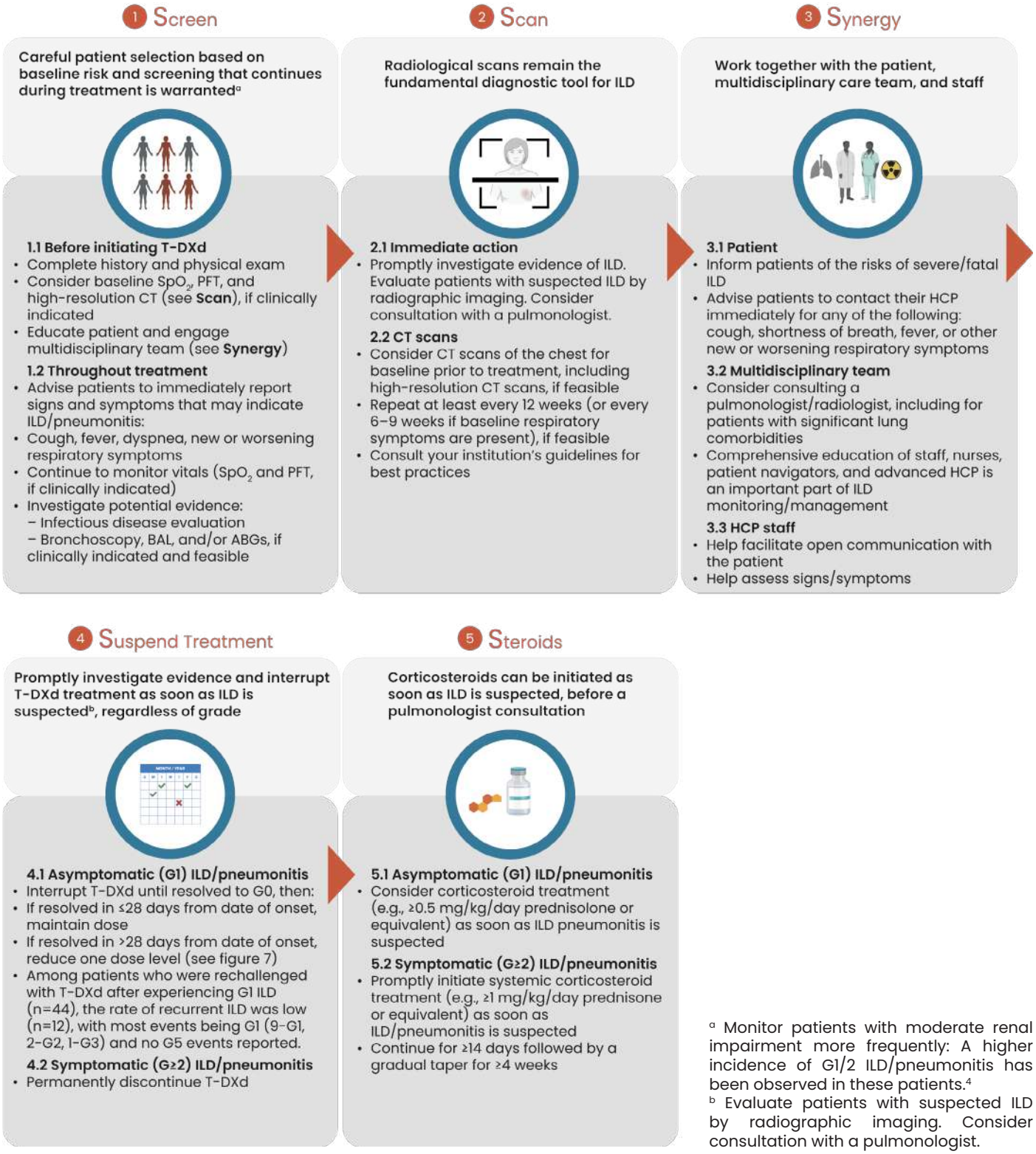
Adjust T-DXd if needed
- Dose reductions may alleviate fatigue
- No cumulative fatigue observed in clinical experience (anecdotal)

Dose reduction schedule[14]

	Breast Cancer
Recommended starting dose	5.4 mg/kg
First dose reduction	4.4 mg/kg
Second dose reduction	3.2 mg/kg
Requirement for further dose reduction	Discontinue

Do not re-escalate the T-DXd dose after a dose reduction is made

Figure 8. The five 'S' strategies to help detect and manage ILD/pneumonitis in patients receiving T-DXd[21,22]



[a] Monitor patients with moderate renal impairment more frequently: A higher incidence of G1/2 ILD/pneumonitis has been observed in these patients.[4]
[b] Evaluate patients with suspected ILD by radiographic imaging. Consider consultation with a pulmonologist.

Additional support

Adequate psychosocial support for all patients is recommended, and holistic approaches can be effective in managing patients. These can include counselling, mind–body techniques, practical support as well as provision of dietary advice from a cancer nurse or dietician. In addition, patients should be advised on the benefits of adequate hydration, and of acupuncture and exercise for AE management.

Abbreviations

ABG	Arterial blood gases
ASCO	American Society of Clinical Oncology
BAL	Bronchoalveolar lavage
BICR	Blinded independent central review
BM	Brain metastases
CI	Confidence interval
CINV	Chemotherapy-induced nausea and vomiting
CNS	Central nervous system
CT	Computed tomography
DOR	Duration of response
EMA	European Medicines Agency
ESMO	European Society for Medical Oncology
FDA	Food and Drug Administration
HER2	Human epidermal growth factor receptor 2
HCPs	Health care professionals
HR (status)	Hormone receptor status
IHC	Immunohistochemistry
ISH	In situ hybridisation
IV	Intravenous
MASCC	Multinational Association of Supportive Care in Cancer
NCCN	National Comprehensive Cancer Network
NK1 RA	Neurokinin-1 receptor antagonist
ORR	Overall response rate
PD	Disease progression
PFT	Pulmonary function test
PO	Per os (oral administration)
Q3W	Every three weeks
SpO_2	Peripheral oxygen saturation
5-HT3 RA	5-hydroxytryptamine-3 receptor antagonist

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Managing T-DXd Side Effects

Guidance to help you recognise and manage side effects confidently

If you are reading this, you may have been prescribed trastuzumab deruxtecan (T-DXd). If you notice any side effects, sharing them with your healthcare team allows you to work together to manage them and continue your treatment as safely and comfortably as possible.

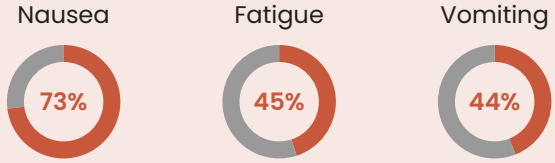
1 What is T-DXd?

T-DXd is a combination of an antibody and chemotherapy. It works by:

- **Targeting:** The antibody recognises and binds to HER2 on the surface of cancer cells
- **Entering:** After binding, the drug is pulled inside the cancer cell
- **Releasing:** Inside the cell, the chemotherapy (DXd) is released
- **Destroying:** DXd kills the cancer cell from within

2 What are the possible side effects?

T-DXd may cause side effects. These can resolve on their own or be managed with your healthcare team. The most frequent are:[1]



Most are mild or moderate (Grade 1–2)

~7% experience more severe nausea needing appropriate medication

Report cough or shortness of breath as soon as possible...

...these can be early signs of ILD, a rare but serious side effect causing lung tissue scarring

3 How are side effects graded and what does that mean for you?

- Your healthcare team uses a 1–5 scale to understand how serious side effects are and decide the best care for you[2]
- With T-DXd, nausea, vomiting, and fatigue are usually mild to moderate and rarely require hospital care[1]
- Be mindful that fatigue may become more noticeable over time after treatment initiation[1]

Most frequent — Rare — Very rare

	Grade 1 (mild)	Grade 2 (moderate)	Grade 3 (severe)	Grade 4 (life-threatening)	Grade 5 (death)
Nausea/ vomiting	• Loss of appetite • Queasiness	• Decrease food intake • Dehydration	• Inadequate caloric or fluid intake	• Hospitalisation • Urgent intervention	• Death related to adverse event
Fatigue	• Relieved by rest	• Not relieved by rest	• Not relieved by rest		
Intervention	• None	• Need of medication	• Hospitalisation • Nutrition via IV or feeding tube		
Daily activities	• Not affected	• Harder but manageable with some help	• Very difficult, need help with activities	• Need help with personal care	

4 Preventing nausea & vomiting

Your healthcare team will recommend preventative medication BEFORE your T-DXd treatment

May include combination of 3–4 medicines tailored to your needs

Symptoms may still occur days or even weeks after T-DXd treatment

If you still notice symptoms, alert your healthcare team and they may adjust your medication

5 What can you do?*

You can also help yourself to minimise the impact of these side effects. Strategies for self-help include:

Physical exercise[3] (for fatigue)

- Weekly 150–300 min moderate intensity
- Or 75–150 min vigorous intensity during the week (10 min intervals)
- Stretching/resistance training 2x per week

Psychosocial support (for all symptoms)

- Emotional, mental, practical support
- Holistic therapies i.e. acupuncture

Dietary changes[4] (for nausea/vomiting)

- Small, frequent meals
- Anti-nausea foods: ginger and lemon
- Avoid strong-smelling, greasy, spicy, or overly sweet foods
- Stay hydrated, eating cold or room-temperature foods

6 Tracking your symptoms between visits*

Tracking tools include:

- Fatigue scales (FSS, FAS, FACIT-Fatigue)
- Simple numerical rating scales (NRS) to rate nausea severity (1–10)
- Rhodes Index of Nausea, Vomiting, and Retching (RINVR) questionnaire

*Check with your healthcare team for best practices.

Report symptoms early. You know your body best!

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Glossary

This glossary is designed to help patients and caregivers better understand common medical terms related to trastuzumab deruxtecan (T-DXd) treatment and its side effects.

Adverse event	A side effect or unwanted medical problem that happens during treatment. It can be mild (like feeling tired) or more serious (like ILD, needing hospitalisation).
Antibody	A special protein that can find and attach to specific targets (like proteins on cancer cells). It acts like a 'guided missile' to help deliver treatment to the right place.
Chemotherapy	A type of medicine that kills cancer cells or stops them from growing. It can also affect healthy cells, which may cause side effects.
Common Terminology Criteria for Adverse Events	A standard way for doctors to describe and grade (rate) side effects from 1 (mild) to 5 (death related to the event). This helps guide treatment decisions.
Complementary therapies	Extra activities or treatments (like acupuncture, relaxation techniques, or gentle exercise) used along with medical treatment to help you feel better.
DXd	The chemotherapy part of trastuzumab deruxtecan that kills cancer cells after it enters them.
Fatigue	A feeling of extreme tiredness or lack of energy that doesn't always get better with rest.
HER2	A protein found on the surface of some cancer cells. Certain breast cancers have too much HER2, and targeted treatments can help attack these cells.
Interstitial lung disease	A rare but serious side effect where the lungs can become inflamed or scarred, causing cough or shortness of breath. It should be reported to your healthcare team immediately.
Moderate/severe (side effects)	These describe how much a side effect impacts your daily life. Moderate might affect some daily tasks, while severe may stop you from doing basic self-care and could require hospital treatment.
Nausea	A feeling of wanting to vomit or feeling sick to your stomach.
Numerical Rating Scale	A simple 1–10 scale where you rate how strong a symptom feels (for example, nausea 1 = mild, 10 = very bad).
Patient advocacy groups	Organisations that offer support, information, and resources to people living with cancer.
Preventative medication	Medicine given before treatment to help stop side effects from happening.
Rhodes Index of Nausea, Vomiting, and Retching	A short questionnaire used to measure how severe nausea and vomiting are, and how much they affect daily life.
Self-help strategies	Things you can do to manage side effects at home, such as gentle exercise, changes to diet, and emotional support.
Side effects	Unwanted symptoms or changes in your health caused by treatment.
T-DXd	Short for trastuzumab deruxtecan, a targeted cancer treatment. It attaches to HER2 proteins on cancer cells and delivers chemotherapy directly inside them.
Targeted therapy	A cancer treatment designed to find and attack specific types of cancer cells, causing less harm to normal cells.
Total parenteral nutrition	A way to give nutrition through a vein when a person cannot eat or drink normally.
Tube feeding	Food and drink delivered directly into the stomach through a small tube inserted in a nostril.

Abbreviations

DXd	Deruxtecan
FACIT	Functional Assessment of Chronic Illness Therapy
FAS	Fatigue Assessment Scale
FSS	Fatigue Severity Scale
HER2	Human epidermal growth factor receptor 2
ILD	Interstitial lung disease
IV	Intravenous

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