Public Assessment Report
TECENTRIQ

INFORMASI PRODUK

Nama obat	:	**TECENTRIQ**
Bentuk sediaan	:	Cairan Konsentrat untuk Infus
Zat aktif	:	Tiap vial mengandung Atezolizumab 1200 mg dan 840 mg
Kemasan	:	Dus, 1 vial @ 20 mL dan Dus, 1 vial @ 14 ml
Pemilik Ijin Edar	:	PT. Menarini Indria Laboratories
Produsen	:	F. Hoffmann-La Roche Ltd., Kaiseraugst, Switzerland
Kategori Registrasi	:	Registrasi produk biologi yang sudah terdaftar dengan indikasi dan posologi baru
Indikasi yang diajukan:	:	**Urothelial Carcinoma (second-line)** Tecentriq is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) after prior platinum-containing chemotherapy. **Early-Stage Non-Small Cell Lung Cancer** Tecentriq as monotherapy is indicated as adjuvant treatment following resection and platinum-based chemotherapy for patients with stage II to IIIA (7th edition of the UICC/AJCC-staging system) NSCLC whose tumors have PD-L1 expression on ≥ 1% of tumor cells (TC). **Metastatic Non-Small Cell Lung Cancer** Tecentriq is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior platinum-containing chemotherapy. Tecentriq as monotherapy is indicated for the first-line treatment of patients with metastatic NSCLC whose tumors have a PD-L1 expression ≥ 50% tumor cells or ≥ 10% tumor-infiltrating immune cells and who do not have EGFR or ALK genomic tumor aberrations. Tecentriq, in combination with bevacizumab, paclitaxel, and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations. Tecentriq as monotherapy is indicated for the first-line treatment of adult patients with NSCLC who are ineligible for platinum-based chemotherapy and who do not have EGFR or ALK genomic tumor aberrations, who have: ● locally advanced, unresectable NSCLC not amenable for definitive chemoradiotherapy, or ● metastatic NSCLC (see section 3.1.2 Clinical / Efficacy Studies). **Small Cell Lung Cancer** Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). **Hepatocellular Carcinoma** Tecentriq, in combination with bevacizumab (Avastin), is indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

Posologi yang diajukan : **General**

Substitution by any other biological medicinal product requires the consent of the prescribing physician.

Tecentriq must be administered as an intravenous infusion under the supervision of a qualified health care professional.

For the use of Tecentriq in combination therapy, please also refer to the full prescribing information for the combination product. Tecentriq should be administered prior to the combination therapy if given on the same day.

Tecentriq IV

Tecentriq IV formulation is not intended for subcutaneous administration.

Tecentriq IV formulation must be administered as an intravenous infusion. Do not administer as an IV push or bolus.

Do not coadminister other medicinal products through the same infusion line.

The initial dose of Tecentriq must be administered over 60 minutes. If the first infusion is tolerated all subsequent infusions may be administered over 30 minutes.

Patient Selection

Early-stage NSCLC, 1L metastatic NSCLC

If specified in the indication, adult patients should be selected for treatment based on the tumor expression of PD-L1, with no EGFR or ALK genomic tumor aberrations, confirmed by a validated test (see section 3.1.2 Clinical/Efficacy Studies).

Table 1 Recommended dose for Tecentriq monotherapy by intravenous (IV) infusion

Indication	**Recommended dose and schedule**	**Duration of treatment** (see section 3.1.2 Clinical / Efficacy Studies)
2L UC	Tecentriq IV ● 840 mg every 2 weeks or ● 1200 mg every 3 weeks or ● 1680 mg every 4 weeks	Until loss of clinical benefit or unmanageable toxicity
1L and 2L NSCLC		Until loss of clinical benefit or unacceptable toxicity
Early-stage NSCLC		For 1 year unless disease recurrence or unacceptable toxicity

Table 2 Recommended dose for Tecentriq combination therapy by intravenous (IV) infusion

Indication	**Recommended dose and schedule**		**Duration of treatment** (see section 3.1.2 Clinical / Efficacy Studies)
	Tecentriq	**Combination medicinal products**	
1L non-squamous metastatic NSCLC: Tecentriq with bevacizumab,	Induction phase: ● 1L non-squamous metastatic NSCLC: Four or six cycles ● 1L ES-	Induction phase: ● Bevacizumab, paclitaxel, and then carboplatin are administered every 3 weeks. Maintenance phase ● Bevacizumab is administered every	Induction phase: ● 1L non-squamous metastatic NSCLC: Four or six cycles ● 1L ES-SCLC: Four

paclitaxel, and carboplatin	SCLC: Four cycles Maintenance phase: ● Until disease progression or unmanageable toxicity.	3 weeks.	cycles Maintenance phase: ● Until disease progression or unmanageable toxicity.
1L ES-SCLC: Tecentriq with carboplatin and etoposide		Induction Phase: ● Carboplatin and etoposide are administered by IV infusion every three weeks. ● Carboplatin and etoposide are administered on day 1 of each cycle, and etoposide is also administered on days 2 and 3.	
HCC: Tecentriq with bevacizumab	Tecentriq IV ● 840 mg every 2 weeks or ● 1200 mg every 3 weeks or ● 1680 mg every 4 weeks	Tecentriq should be administered prior to bevacizumab when given on the same day. Bevacizumab is administered at 15 mg/kg body weight (bw) every 3 weeks.	Until loss of clinical benefit or unmanageable toxicity.

Delayed or Missed Doses

If a planned dose of Tecentriq is missed, it should be administered as soon as possible. The schedule of administration should be adjusted to maintain the appropriate interval between doses.

Dose Modifications

No dose reductions of Tecentriq are recommended.

Dose Modifications for Immune-Mediated Adverse Reactions

Recommendations for specific adverse drug reactions (see sections 2.4.1 Warnings and Precautions, General and 2.6.1 Undesirable Effects, Clinical Trials) are presented in Table 3.

Table 3 Recommended dose modifications for specific adverse drug reactions

Adverse Drug Reaction	Severity	Treatment Modification
Immune-mediated pneumonitis	Grade 2	Withhold[1]
	Grade 3 or 4	Permanently discontinue

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Adverse Drug Reaction	Severity	Treatment Modification
Immune-mediated hepatitis in patients without HCC	Grade 2 (ALT or AST > 3x ULN or blood bilirubin > 1.5x ULN for more than 5-7 days)	Withhold[1]
	Grade 3 or 4 (ALT or AST > 5.0x ULN or blood bilirubin > 3x ULN)	Permanently discontinue
Immune-mediated hepatitis in patients with HCC	If AST/ALT is within normal limits at baseline and increases to > 3x to ≤ 10x ULN If AST/ALT is > 1 to ≤ 3x ULN at baseline and increases to > 5x to ≤ 10x ULN If AST/ALT is > 3x to ≤ 5x ULN at baseline and increases to > 8x to ≤ 10x ULN	Withhold[1]
	If AST/ALT increases to > 10x ULN or total bilirubin increases to > 3x ULN	Permanently discontinue
Immune-mediated colitis	Grade 2 diarrhoea or colitis	Withhold[1]
	Grade 3 diarrhoea or colitis	Withhold[1] Initiate IV corticosteroids and convert to oral corticosteroids after improvement
	Grade 4 diarrhoea or colitis	Permanently discontinue
Immune-mediated hypothyroidism	Symptomatic	Withhold[2] Initiate thyroid hormone replacement therapy
Immune-mediated hyperthyroidism	Symptomatic	Withhold[2] Initiate antithyroid therapy as needed
Immune-mediated adrenal insufficiency	Symptomatic	Withhold[1]

Adverse Drug Reaction	Severity	Treatment Modification
Immune-mediated hypophysitis	Grade 2 or 3	Withhold[1]
	Grade 4	Permanently discontinue
Immune-mediated type 1 diabetes	For ≥ Grade 3 hyperglycemia (fasting glucose > 250 mg/dL)	Withhold[2] Initiate insulin
Immune-mediated meningitis, encephalitis, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome	All grades	Permanently discontinue
Immune-mediated myelitis	Grade 2,3 or 4	Permanently discontinue
Immune-mediated facial paresis	Grade 1 or 2	Withhold[1]
	Grade 3 or 4	Permanently discontinue
Immune-mediated pancreatitis	Grade 2 or 3 ≥ Grade 3 serum amylase or lipase levels increased (> 2.0 ULN)	Withhold[1]
	Grade 4 or any grade recurrent pancreatitis	Permanently discontinue
Immune-mediated myocarditis	Grade 2 or above	Permanently discontinue
Immune-mediated myositis	Grade 2 or 3	Withhold[1]
	Grade 4 or Grade 3 recurrent myositis	Permanently discontinue
Immune-mediated nephritis	Grade 2 (creatinine level > 1.5 - 3.0x baseline or > 1.5 - 3.0x ULN)	Withhold[1]
	Grade 3 (creatinine level > 3.0x baseline or > 3.0 - 6.0x ULN) or 4 (creatinine level > 6.0x ULN)	Permanently discontinue
Immune-mediated pericardial disorders	Grade 1 pericarditis	Withhold[3]
	Grade 2 or above	Permanently discontinue

Adverse Drug Reaction	Severity	Treatment Modification
Infusion-related reactions	Grade 1 or 2	Reduce rate of infusion or withhold treatment Premedication with antipyretic and antihistamines may be considered for subsequent doses
	Grade 3 or 4	Permanently discontinue
Haemophagocytic lymphohistiocytosis	Suspected haemophagocytic lymphohistiocytosis[4]	Permanently discontinue
Rash/Severe cutaneous adverse reactions	Grade 3 or suspected Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)[3]	Withhold[1]
	Grade 4 or confirmed Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)[3]	Permanently discontinue

[1] Treatment with corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. Treatment with Tecentriq may be resumed in patients with complete or partial resolution (Grade 0 to 1) within 12 weeks, and after corticosteroids have been reduced to ≤ 10 mg/day oral prednisone or equivalent.
[2] Treatment with Tecentriq may be resumed when symptoms are controlled and the patient is clinically stable.
[3] Conduct a detailed cardiac evaluation to determine the etiology and manage appropriately.
[4] Regardless of severity.

For other immune-mediated reactions, based on the type and severity of the reaction, treatment with Tecentriq should be withheld for Grades 2 or 3 immune-mediated adverse reactions and corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. If symptoms improve to ≤ Grade 1, taper corticosteroids as clinically indicated. Treatment with Tecentriq may be resumed if the event improves to ≤ Grade 1 within 12 weeks, and corticosteroids have been reduced to ≤ 10 mg oral prednisone or equivalent per day.
Treatment with Tecentriq should be permanently discontinued for Grade 4 immune-mediated adverse reactions, or when unable to reduce corticosteroid dose to the equivalent of ≤ 10 mg prednisone per day within 12 weeks after onset.

Special Dosage Instructions
Pediatric use
The safety and efficacy of Tecentriq in children and adolescents below 18 years of age have not been established (see sections 2.5.4 Pediatric Use and 3.2.5 Pharmacokinetics in Special Populations).
Geriatric use
Based on a population pharmacokinetic analysis, no dose adjustment of Tecentriq is required in patients ≥ 65 years of age (see sections 2.5.5 Geriatric Use and 3.2.5 Pharmacokinetics in Special Populations).
Renal impairment
Based on a population pharmacokinetic analysis, no dose adjustment is required in patients with renal impairment (see section 3.2.5 Pharmacokinetics in Special Populations).
Hepatic impairment
Based on a population pharmacokinetic analysis, no dose adjustment is required for patients with mild or moderate hepatic impairment. There are no data in patients with severe hepatic impairment (see section 3.2.5 Pharmacokinetics in Special Populations).

Dirilis oleh BPOM tanggal 22 Juli 2026

PENGANTAR

Tecentriq yang mengandung zat aktif Atezolizumab, sudah memiliki izin edar di Indonesia, dengan indikasi yang disetujui untuk Urothelial Carcinoma (second-line), Early-Stage Non-Small Cell Lung Cancer, Metastatic Non-Small Cell Lung Cancer, Small Cell Lung Cancer, Hepatocellular Carcinoma. Saat ini pendaftar mengajukan penambahan indikasi baru, yaitu "Tecentriq as monotherapy is indicated for the first-line treatment of adult patients with NSCLC who are ineligible for platinum-based chemotherapy and who do not have EGFR or ALK genomic tumor aberrations, who have: locally advanced, unresectable NSCLC not amenable for definitive chemoradiotherapy, or metastatic NSCLC (see section 3.1.2 Clinical / Efficacy Studies).

Karena merupakan pengajuan indikasi baru, maka evaluasi akan dilakukan berdasarkan hasil studi klinik yang telah tersedia sebelumnya, dengan mempertimbangkan data efikasi dan keamanan yang ada serta justifikasi yang disampaikan pendaftar terkait interchangeability regimen dosis dan penetapan kriteria inklusi pasien yang ineligible untuk kemoterapi berbasis platinum, sebagai dasar pembahasan dalam Rapat Komite Nasional Penilai Obat.

ASPEK KHASIAT DAN KEAMANAN

Studi Non Klinik

Tidak ada data non klinik baru yang diserahkan

Studi Klinik

Berdasarkan hasil penilaian dan pembahasan pada Rapat Komite Nasional Penilai Obat tanggal 4 Juni 2024 sebagaimana tercantum dalam Surat Hasil Evaluasi Khasiat dan Keamanan nomor RG.01.02.322.12.24.03110/T tanggal 4 Desember 2024 dan nomor RG.01.02.322.06.24.02701/T tanggal 10 Juni 2024, *Overall Survival* dan *Objective Response Rate* lebih baik pada kelompok Atezolizumab dibandingkan plasebo, sementara untuk parameter *Progression Free Survival* tidak berbeda bermakna. Profil keamanan menunjukkan *Adverse Events* (*AEs*) yang terjadi pada studi ini secara umum konsisten dengan profil keamanan Atezolizumab yang sudah diketahui.

Pada saat pengajuan ini, disampaikan justifikasi terkait interchangeability dan kriteria inklusi dapat dipertimbangkan:

- Interchangeability antara rejimen 1200 mg q3w dengan 840 mg q2w dan 1680 mg q4w pada pemberian monoterapi untuk subjek dengan NSCLC telah dibuktikan berdasarkan studi modeling farmakokinetik, analisis exposure-response, baik pada parameter efikasi maupun keamanan, dan telah dievaluasi pada registrasi sebelumnya.
- Kriteria inklusi ineligible platinum-based chemotherapy ditentukan tidak hanya mempertimbangkan ECOG performance status, namun juga berdasarkan penilaian oleh investigator. Penetapan kriteria tersebut juga dilakukan berdasarkan pedoman *ESMO* (*European Society for Medical Oncology*).

EVALUASI

Penilaian Manfaat-Risiko

Tecentriq, dengan zat aktif Atezolizumab merupakan antibodi monoklonal humanized immunoglobulin G1 (IgG1) yang bekerja sebagai *immune checkpoint inhibitor* dengan menghambat interaksi PD-L1 terhadap reseptor PD-1 dan B7.1. Produk ini telah memiliki izin edar di Indonesia untuk indikasi *Urothelial Carcinoma (second-line), Early-Stage Non-Small Cell Lung Cancer, Metastatic Non-Small Cell Lung Cancer, Small Cell Lung Cancer, Hepatocellular Carcinoma.*

Saat ini, pendaftar mengajukan perluasan indikasi Tecentriq sebagai monoterapi lini pertama untuk pasien dewasa dengan *NSCLC* lokal lanjut yang tidak dapat direseksi atau tidak dapat ditangani dengan kemoradioterapi kuratif, serta pasien dengan *NSCLC* metastatik, yang tidak memiliki aberasi genom EGFR atau ALK, dan dinilai tidak layak untuk kemoterapi berbasis platinum.

Berdasarkan hasil studi khasiat dan keamanan, Atezolizumab memiliki efek yang menguntungkan, efek yang tidak menguntungkan, ketidakpastian dan keterbatasan sebagai berikut.

a) Aspek yang menguntungkan:
    1. Efikasi klinik telah dibuktikan melalui studi:

- Hasil studi menunjukkan *Overall Survival* (*OS*) dan *Objective Response Rate* (*ORR*) lebih baik secara bermakna pada kelompok Atezolizumab dibandingkan plasebo.
- Walaupun *Progression-Free Survival* (*PFS*) tidak menunjukkan perbedaan bermakna, manfaat klinik dari peningkatan *OS* menjadi dasar penting dukungan terhadap indikasi baru.

2. *Adverse Events* (*AEs*) yang muncul konsisten dengan profil keamanan Atezolizumab yang telah diketahui pada indikasi sebelumnya, tanpa temuan sinyal baru yang signifikan.
3. Fleksibilitas regimen dosis berdasarkan data farmakokinetik dan analisis exposure–response mendukung *interchangeability* antar rejimen (1200 mg q3w, 840 mg q2w, dan 1680 mg q4w) untuk monoterapi NSCLC, baik dari aspek efikasi maupun keamanan.
4. Tersedianya pilihan terapi baru bagi pasien NSCLC stadium lanjut/metastatik yang ineligible untuk kemoterapi berbasis platinum, di mana opsi pengobatan sangat terbatas, sehingga memberikan manfaat klinis signifikan.

b) Aspek yang tidak menguntungkan
1. *PFS* tidak berbeda bermakna, sehingga walaupun *OS* meningkat, sebagian pasien mungkin tidak mengalami perbaikan dalam kendali penyakit jangka menengah.
2. Populasi tertentu tidak tercakup, misalnya pasien dengan mutasi EGFR/ALK, karena belum ada bukti klinis memadai pada kelompok tersebut

c) Ketidakpastian dan keterbatasan
- Interpretasi kriteria *ineligible platinum-based chemotherapy* bervariasi, karena ditentukan tidak hanya oleh ECOG performance status, tetapi juga berdasarkan penilaian investigator.
- Data real-world evidence untuk indikasi baru di Indonesia belum tersedia, sehingga manfaat–risiko jangka panjang dalam konteks lokal masih harus ditinjau melalui pemantauan pasca pemasaran.

Kesimpulan evaluasi manfaat-risiko:
Berdasarkan hasil evaluasi, penambahan indikasi Atezolizumab sebagai monoterapi lini pertama untuk pasien dewasa dengan NSCLC stadium lanjut/metastatik yang tidak layak mendapat kemoterapi berbasis platinum dan tanpa aberasi EGFR/ALK menunjukkan manfaat klinis yang signifikan, terutama dalam peningkatan overall survival, dengan profil keamanan yang dapat diterima dan konsisten dengan data sebelumnya.
Meskipun terdapat keterbatasan pada data PFS, rasio manfaat–risiko secara keseluruhan dinilai positif, sehingga mendukung persetujuan perluasan indikasi ini dengan pemantauan keamanan berkelanjutan melalui pharmacovigilance.
Namun, efektivitas yang tidak signifikan pada subpopulasi tertentu dan terbatasnya pengalaman pasca-pemasaran perlu menjadi pertimbangan dalam pemantauan lanjutan sehingga dapat disimpulkan manfaat Atezolizumab untuk indikasi yang diajukan dapat diterima, dengan syarat pemantauan ketat terhadap keamanan dan implementasi strategi mitigasi risiko sesuai RMP.

KEPUTUSAN

Mempertimbangkan hasil studi khasiat dan keamanan di atas, maka registrasi obat yang sudah terdaftar dengan indikasi baru Atezolizumab cairan konsentrat untuk infus **diterima dengan perbaikan redaksi indikasi** menjadi sebagai berikut:

Indikasi:

Urothelial Carcinoma (second-line)

Tecentriq is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) after prior platinum-containing chemotherapy.

Early-Stage Non-Small Cell Lung Cancer

Tecentriq as monotherapy is indicated as adjuvant treatment following resection and platinum-based chemotherapy for patients with stage II to IIIA (7th edition of the UICC/AJCC-staging system) NSCLC whose tumors have PD-L1 expression on ≥ 1% of tumor cells (TC).

Metastatic Non-Small Cell Lung Cancer

Tecentriq is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior platinum-containing chemotherapy.

Tecentriq as monotherapy is indicated for the first-line treatment of patients with metastatic NSCLC whose tumors have a PD-L1 expression ≥ 50% tumor cells or ≥ 10% tumor-infiltrating immune cells and who do not have EGFR or ALK genomic tumor aberrations.

Tecentriq, in combination with bevacizumab, paclitaxel, and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.

Tecentriq as monotherapy is indicated for the first-line treatment of adult patients with NSCLC who are ineligible for platinum-based chemotherapy and who do not have EGFR or ALK genomic tumor aberrations, who have:

- locally advanced, unresectable NSCLC not amenable for definitive chemoradiotherapy, or
- metastatic NSCLC (see section 3.1.2 Clinical / Efficacy Studies).

Small Cell Lung Cancer

Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC).

Hepatocellular Carcinoma

Tecentriq, in combination with bevacizumab (Avastin), is indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy

Posologi:

General

Substitution by any other biological medicinal product requires the consent of the prescribing physician.

Tecentriq must be administered as an intravenous infusion under the supervision of a qualified health care professional.

For the use of Tecentriq in combination therapy, please also refer to the full prescribing information for the combination product. Tecentriq should be administered prior to the combination therapy if given on the same day.

Tecentriq IV

Tecentriq IV formulation is not intended for subcutaneous administration.

Tecentriq IV formulation must be administered as an intravenous infusion. Do not administer as an IV push or bolus.

Do not coadminister other medicinal products through the same infusion line.

The initial dose of Tecentriq must be administered over 60 minutes. If the first infusion is tolerated all subsequent infusions may be administered over 30 minutes.

Patient Selection

Early-stage NSCLC, 1L metastatic NSCLC

If specified in the indication, adult patients should be selected for treatment based on the tumor expression of PD-L1, with no EGFR or ALK genomic tumor aberrations, confirmed by a validated test (see section 3.1.2 Clinical/Efficacy Studies).

Table 1 Recommended dose for Tecentriq monotherapy by intravenous (IV) infusion

Indication	**Recommended dose and schedule**	**Duration of treatment** (see section 3.1.2 Clinical / Efficacy Studies)
2L UC	Tecentriq IV ● 840 mg every 2 weeks or ● 1200 mg every 3 weeks or ● 1680 mg every 4 weeks	Until loss of clinical benefit or unmanageable toxicity
1L and 2L NSCLC		Until loss of clinical benefit or unacceptable toxicity
Early-stage NSCLC		For 1 year unless disease recurrence or unacceptable toxicity

Table 2 Recommended dose for Tecentriq combination therapy by intravenous (IV) infusion

Indication	**Recommended dose and schedule**		**Duration of treatment** (see section 3.1.2 Clinical / Efficacy Studies)
	Tecentriq	**Combination medicinal products**	
1L non-squamous metastatic NSCLC: Tecentriq with bevacizumab, paclitaxel, and carboplatin	Induction phase: ● 1L non-squamous metastatic NSCLC: Four or six cycles ● 1L ES-SCLC: Four cycles Maintenance phase: ● Until disease progression or unmanageable toxicity.	Induction phase: ● Bevacizumab, paclitaxel, and then carboplatin are administered every 3 weeks. Maintenance phase ● Bevacizumab is administered every 3 weeks.	Induction phase: ● 1L non-squamous metastatic NSCLC: Four or six cycles ● 1L ES-SCLC: Four cycles Maintenance phase: ● Until disease progression or unmanageable toxicity.
1L ES-SCLC: Tecentriq with carboplatin and etoposide		Induction Phase: ● Carboplatin and etoposide are administered by IV infusion every three weeks. ● Carboplatin and etoposide are administered on day 1 of each cycle, and etoposide is also administered on days 2 and 3.	
HCC: Tecentriq with bevacizumab	Tecentriq IV ● 840 mg every 2 weeks or ● 1200 mg every 3 weeks or ● 1680 mg every 4 weeks	Tecentriq should be administered prior to bevacizumab when given on the same day. Bevacizumab is administered at 15 mg/kg body weight (bw) every 3 weeks.	Until loss of clinical benefit or unmanageable toxicity.

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Delayed or Missed Doses

If a planned dose of Tecentriq is missed, it should be administered as soon as possible. The schedule of administration should be adjusted to maintain the appropriate interval between doses.

Dose Modifications

No dose reductions of Tecentriq are recommended.

Dose Modifications for Immune-Mediated Adverse Reactions

Recommendations for specific adverse drug reactions (see sections 2.4.1 Warnings and Precautions, General and 2.6.1 Undesirable Effects, Clinical Trials) are presented in Table 3.

Table 3 Recommended dose modifications for specific adverse drug reactions

Adverse Drug Reaction	Severity	Treatment Modification
Immune-mediated pneumonitis	Grade 2	Withhold[1]
	Grade 3 or 4	Permanently discontinue

Adverse Drug Reaction	Severity	Treatment Modification
Immune-mediated hepatitis in patients without HCC	Grade 2 (ALT or AST > 3x ULN or blood bilirubin > 1.5x ULN for more than 5-7 days)	Withhold[1]
	Grade 3 or 4 (ALT or AST > 5.0x ULN or blood bilirubin > 3x ULN)	Permanently discontinue
Immune-mediated hepatitis in patients with HCC	If AST/ALT is within normal limits at baseline and increases to > 3x to ≤ 10x ULN If AST/ALT is > 1 to ≤ 3x ULN at baseline and increases to > 5x to ≤ 10x ULN If AST/ALT is > 3x to ≤ 5x ULN at baseline and increases to > 8x to ≤ 10x ULN	Withhold[1]
	If AST/ALT increases to > 10x ULN or total bilirubin increases to > 3x ULN	Permanently discontinue
Immune-mediated colitis	Grade 2 diarrhoea or colitis	Withhold[1]
	Grade 3 diarrhoea or colitis	Withhold[1] Initiate IV corticosteroids and convert to oral corticosteroids after improvement
	Grade 4 diarrhoea or colitis	Permanently discontinue
Immune-mediated hypothyroidism	Symptomatic	Withhold[2] Initiate thyroid hormone replacement therapy
Immune-mediated hyperthyroidism	Symptomatic	Withhold[2] Initiate antithyroid therapy as needed
Immune-mediated adrenal insufficiency	Symptomatic	Withhold[1]

Adverse Drug Reaction	Severity	Treatment Modification
Immune-mediated hypophysitis	Grade 2 or 3	Withhold[1]
	Grade 4	Permanently discontinue
Immune-mediated type 1 diabetes	For ≥ Grade 3 hyperglycemia (fasting glucose > 250 mg/dL)	Withhold[2] Initiate insulin
Immune-mediated meningitis, encephalitis, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome	All grades	Permanently discontinue
Immune-mediated myelitis	Grade 2,3 or 4	Permanently discontinue
Immune-mediated facial paresis	Grade 1 or 2	Withhold[1]
	Grade 3 or 4	Permanently discontinue
Immune-mediated pancreatitis	Grade 2 or 3 ≥ Grade 3 serum amylase or lipase levels increased (> 2.0 ULN)	Withhold[1]
	Grade 4 or any grade recurrent pancreatitis	Permanently discontinue
Immune-mediated myocarditis	Grade 2 or above	Permanently discontinue
Immune-mediated myositis	Grade 2 or 3	Withhold[1]
	Grade 4 or Grade 3 recurrent myositis	Permanently discontinue
Immune-mediated nephritis	Grade 2 (creatinine level > 1.5 - 3.0x baseline or > 1.5 - 3.0x ULN)	Withhold[1]
	Grade 3 (creatinine level > 3.0x baseline or > 3.0 - 6.0x ULN) or 4 (creatinine level > 6.0x ULN)	Permanently discontinue
Immune-mediated pericardial disorders	Grade 1 pericarditis	Withhold[3]
	Grade 2 or above	Permanently discontinue

Adverse Drug Reaction	Severity	Treatment Modification
Infusion-related reactions	Grade 1 or 2	Reduce rate of infusion or withhold treatment Premedication with antipyretic and antihistamines may be considered for subsequent doses
	Grade 3 or 4	Permanently discontinue
Haemophagocytic lymphohistiocytosis	Suspected haemophagocytic lymphohistiocytosis[4]	Permanently discontinue
Rash/Severe cutaneous adverse reactions	Grade 3 or suspected Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)[3]	Withhold[1]
	Grade 4 or confirmed Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)[3]	Permanently discontinue

[1] Treatment with corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. Treatment with Tecentriq may be resumed in patients with complete or partial resolution (Grade 0 to 1) within 12 weeks, and after corticosteroids have been reduced to ≤ 10 mg/day oral prednisone or equivalent.
[2] Treatment with Tecentriq may be resumed when symptoms are controlled and the patient is clinically stable.
[3] Conduct a detailed cardiac evaluation to determine the etiology and manage appropriately.
[4] Regardless of severity.

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Adverse Drug Reaction	Severity	Treatment Modification
Infusion-related reactions	Grade 1 or 2	Reduce rate of infusion or withhold treatment Premedication with antipyretic and antihistamines may be considered for subsequent doses
	Grade 3 or 4	Permanently discontinue
Haemophagocytic lymphohistiocytosis	Suspected haemophagocytic lymphohistiocytosis[4]	Permanently discontinue
Rash/Severe cutaneous adverse reactions	Grade 3 or suspected Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)[3]	Withhold[1]
	Grade 4 or confirmed Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)[3]	Permanently discontinue

[1] Treatment with corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) should be initiated. Treatment with Tecentriq may be resumed in patients with complete or partial resolution (Grade 0 to 1) within 12 weeks, and after corticosteroids have been reduced to ≤ 10 mg/day oral prednisone or equivalent.
[2] Treatment with Tecentriq may be resumed when symptoms are controlled and the patient is clinically stable.
[3] Conduct a detailed cardiac evaluation to determine the etiology and manage appropriately.
[4] Regardless of severity.