SCLC

LIMITED- AND EXTENSIVE-STAGE

IMFINZI EPIC® EHR System Guide

Tipsheet for Order Sets, Patient Lists, and EHR Alerts

Indication:

- IMFINZI, as a single agent, is indicated for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT). IMFINZI, in combination with etoposide and either carboplatin or cisplatin, is indicated for the firstline treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

IMPORTANT SAFETY INFORMATION

There are no contraindications for IMFINZI® (durvalumab).

Immune-Mediated Adverse Reactions

Important immune-mediated adverse reactions listed under Warnings and Precautions may not include all possible severe and fatal immune-mediated reactions. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting treatment or after discontinuation. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate. Withhold or permanently discontinue IMFINZI depending on severity. See USPI Dosing and Administration for specific details. In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

EHR=electronic health record.

Please see Important Safety Information on pages 31 to 34 and Full Prescribing Information including Medication Guide for IMFINZI.

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Table of Contents

SCLC=small cell lung cancer.

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Updating Small Cell Lung Cancer (SCLC) Treatment Plans with IMFINZI Injection, for Intravenous Use

Overview and Limitations

- This document is intended to provide health systems with instructions to update treatment plans for the Epic® EHR system with the following approved indications consistent with Prescribing Information[1]:
  - as a single agent, for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT)
  - in combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)
- This guide is for the Epic EHR system and is not appropriate for other conditions, treatments, or therapeutic areas, or for other EHR systems. This guide is not endorsed, certified, or sponsored by Epic. Epic is not affiliated with AstraZeneca products and services
- The process outlined in this document is variable, and not all steps will apply to every organization. Any steps or settings that are not part of an organization's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The organization is solely responsible for implementing, testing, monitoring, and the ongoing operation of any EHR tools

Considerations

- Treatment plans are commonly used in the management of oncology patients—your organization may refer to these as Beacon plans, treatment regimens, or protocols. After their initial release, treatment plans may benefit from clinical updates to incorporate new products or new indications. The optimization of treatment plans is a common process and provides an opportunity to incorporate treatment updates. Treatment plans are typically modified at the health system level to help reduce practice variation
- Typically, an organization will conduct a clinical review to confirm and approve the suggested optimization. Various stakeholders may participate in reviewing treatment plan optimization requests prior to implementation

Updating SCLC Treatment Plans with IMFINZI Injection, for Intravenous Use (cont'd)

Suggested Treatment Plan

IMFINZI is a programmed death-ligand 1 (PD-L1) blocking antibody indicated[1]:

- as a single agent, for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT)
- in combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)

Key clinical details from the IMFINZI Prescribing Information are included below and may be incorporated as part of the treatment plan update, based on steps in the instructions section that follows. The instructions are not fully inclusive of all details of the IMFINZI Prescribing Information. The Prescribing Information in this section is only suggestive, and it is strongly recommended that clinical and operational leadership align the treatment plan contents with the expectations and goals of the organization. The organization may add or edit any details as desired to align with governing EHR policies and standards.

Please consult the most recent version of the IMFINZI Prescribing Information for full medication details.

Dosage and administration

RECOMMENDED DOSAGES OF IMFINZI[1]

Administer IMFINZI as an intravenous infusion after dilution as recommended (*see Preparation and Administration (2.4)*).

Indication	Recommended IMFINZI Dosage	Duration of Therapy
Single Agent		
LS-SCLC without progression following platinum-based cCRT	Following concurrent platinum-based chemotherapy and radiation therapy: • Patients with a body weight of ≥30 kg: 1500 mg every 4 weeks • Patients with a body weight of <30 kg: 20 mg/kg every 4 weeks	Until disease progression, unacceptable toxicity, or a maximum of 24 months
Combination with Other Therapeutic Agents		
First-line ES-SCLC in combination with etoposide and either carboplatin or cisplatin	• Patients with a body weight of ≥30 kg: 1500 mg in combination with chemotherapy* every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks as a single agent • Patients with a body weight of <30 kg: 20 mg/kg in combination with chemotherapy* every 3 weeks (21 days) for 4 cycles, followed by 10 mg/kg every 2 weeks as a single agent	Until disease progression or unacceptable toxicity

*Administer IMFINZI prior to chemotherapy on the same day. Refer to clinical practice guidelines for the agent administered in combination with IMFINZI for recommended dosage information, as appropriate.[1]

Updating SCLC Treatment Plans with IMFINZI Injection, for Intravenous Use (cont'd)

Dosage modifications[1]

No dose reduction for IMFINZI is recommended. In general, withhold IMFINZI for severe (Grade 3) immune-mediated adverse reactions. Permanently discontinue IMFINZI for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating corticosteroids.

Dosage modifications for IMFINZI or IMFINZI in combination with chemotherapy for adverse reactions that require management different from these general guidelines are summarized in below.

RECOMMENDED DOSAGE MODIFICATIONS FOR ADVERSE REACTIONS[1]

Adverse Reaction	Severity*	Dosage Modification
Immune-Mediated Adverse Reactions [*see IMFINZI Prescribing Information Section 5.1 Warnings and Precautions*]		
Pneumonitis	Grade 2	Withhold†
	Grade 3 or 4	Permanently discontinue
Colitis	Grade 2 or 3	Withhold†
	Grade 4	Permanently discontinue
Intestinal perforation	Any grade	Permanently discontinue
Hepatitis with no tumor involvement of the liver	ALT or AST increases to more than 3 and up to 8 times the ULN or Total bilirubin increases to more than 1.5 and up to 3 times ULN	Withhold†
	ALT or AST increases to more than 8 times ULN or Total bilirubin increases to more than 3 times the ULN	Permanently discontinue
Hepatitis with tumor involvement of the liver‡	AST or ALT is more than 1 and up to 3 times ULN at baseline and increases to more than 5 and up to 10 times ULN or AST or ALT is more than 3 and up to 5 times ULN at baseline and increases to more than 8 and up to 10 times ULN	Withhold†

ALT=alanine aminotransferase; AST=aspartate aminotransferase; ULN=upper limit normal.

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.[1]

†Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating corticosteroids or an inability to reduce corticosteroid dose to 10 mg of prednisone or less per day (or equivalent) within 12 weeks of initiating corticosteroids.[1]

‡If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue IMFINZI based on recommendations for hepatitis with no liver involvement.[1]

Please see Important Safety Information on pages 31 to 34 and Full Prescribing Information including Medication Guide for IMFINZI.

IMFINZI® durvalumab
Injection for Intravenous Use 50 mg/mL

Updating SCLC Treatment Plans with IMFINZI Injection, for Intravenous Use (cont'd)

Dosage modifications (cont'd)[1]

RECOMMENDED DOSAGE MODIFICATIONS FOR ADVERSE REACTIONS (CONT'D)[1]

Adverse Reaction	Severity*	Dosage Modification
Immune-Mediated Adverse Reactions [*see IMFINZI Prescribing Information Section 5.1 Warnings and Precautions*]		
Hepatitis with tumor involvement of the liver‡	AST or ALT increases to more than 10 times ULN or Total bilirubin increases to more than 3 times ULN	Permanently discontinue
Endocrinopathies	Grade 3 or 4	Withhold until clinically stable or permanently discontinue depending on severity
Nephritis with Renal Dysfunction	Grade 2 or 3 increased blood creatinine	Withhold†
	Grade 4 increased blood creatinine	Permanently discontinue
Exfoliative Dermatologic Conditions	Suspected SJS, TEN, or DRESS	Withhold†
	Confirmed SJS, TEN, or DRESS	Permanently discontinue
Myocarditis	Grade 2, 3, or 4	Permanently discontinue
Neurological Toxicities	Grade 2	Withhold†
	Grade 3 or 4	Permanently discontinue
Other Adverse Reactions[1]		
Infusion-related reactions [*see IMFINZI Prescribing Information Section 5.2 Warnings and Precautions*]	Grade 1 or 2	Interrupt or slow the rate of infusion
	Grade 3 or 4	Permanently discontinue

DRESS=Drug Rash with Eosinophilia and Systemic Symptoms; SJS=Stevens-Johnson Syndrome; TEN=toxic epidermal necrolysis.

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03.[1]

†Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating corticosteroids or an inability to reduce corticosteroid dose to 10 mg of prednisone or less per day (or equivalent) within 12 weeks of initiating corticosteroids.[1]

‡If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue IMFINZI based on recommendations for hepatitis with no liver involvement.[1]

For preparation and administration, see section 2.4 of the IMFINZI Prescribing Information.

There are no contraindications for IMFINZI.

Suggested Treatment Plan and Order Set Instructions

An existing treatment plan may be used as the foundation for a new one. Consider modifying an existing treatment plan that includes IMFINZI as a starting template, while saving the original protocol. Consider creating a unique treatment plan for each of the approved indications.

The steps below detail the steps to create two treatment plans:

1. **IMFINZI as a single agent, after cCRT for LS-SCLC**
2. **IMFINZI for 1L ES-SCLC in combination with etoposide and either carboplatin or cisplatin**

IMPORTANT NOTE

The ES-SCLC treatment plan can be created in different ways. The first option is to create a **complete treatment plan of IMFINZI in combination with chemotherapy followed by IMFINZI monotherapy** (after completing the first 4 cycles of IMFINZI in combination with chemotherapy). The second option is to **manually add the IMFINZI monotherapy** (maintenance phase) to a treatment plan that only includes the initial phase of IMFINZI in combination with chemotherapy or creating a separate protocol for the maintenance phase. Please select the appropriate treatment plan built based on guiding EHR governing rules. When opting to create a treatment plan for the IMFINZI initial phase with chemotherapy only and manually adding IMFINZI monotherapy, consider adding a clinical decision support solution (hard or soft alert) to alert the clinician during the 4th, and final cycle of IMFINZI in combination with chemotherapy, to populate and authorize the IMFINZI monotherapy maintenance phase.

There are 3 main steps to updating a treatment plan in the Epic® EHR system:

- **Step 1: Create or update the order groups.** As part of this step, multiple order groups related to IMFINZI may be created/updated. Order groups for IMFINZI and premedication may be created, as well as for any other desired order groups (eg, treatment conditions, monitoring and hold parameters, Warnings and Precautions, supportive care, schedulable orders, HCP communications, hydration, and other sections as desired). Review your organization's governing rules and principles regarding the treatment plan and adjust the optimization appropriately. The same order groups may be used in the different treatment plans.
- **Step 2: Add links** for the Prescribing Information and other resources to the medication record
- **Step 3: Add the order groups** created in Step 1 to the new treatment plan

1L=first-line; cCRT=concurrent chemoradiotherapy; HCP=healthcare professional.

Suggested Treatment Plan and Order Set Instructions (cont'd)

Step 1: Create or Update the Order Groups

1. Review the Regimen Category Order Group to confirm that Medications, Premedications, Treatment Conditions, and Supportive Medications are values in the category list
2. Select the Order Group Builder (Admin > Beacon Admin > Order Group Builder)
3. Create the new order groups (see detailed examples below)

Order Group 1: IMFINZI after cCRT for LS-SCLC

1. Review the **Regimen Category Order Group** to confirm **Medications** is a value in the category list
2. Select the **Order Group Builder** (Admin > Beacon Admin > Order Group Builder)
3. Create a **new order group** named "IMFINZI for LS-SCLC"
4. Set the default category to **Medications**
5. Add the **details** for IMFINZI to the order group:
   - Right click in the empty field at the bottom of the window
   - Select Add Orders > choose IMFINZI
   - Complete the medication details for IMFINZI. Details may include Sig (instructions), dose, route, frequency, offset time, admin over, and any free-form special admin instructions for the nurse:
     - The recommended dosage of IMFINZI is[1]:
       - Patients with a body weight of ≥30 kg: 1500 mg every 4 weeks
       - Patients with a body weight of <30 kg: 20 mg/kg every 4 weeks
     - Until disease progression, unacceptable toxicity, or a maximum of 24 months[1]
6. Once all the desired information is added, release the Order Group to the production environment after completing testing

Order Group 1: IMFINZI for ES-SCLC

1. Review the **Regimen Category Order Group** to confirm that **Medications** is a value in the category list
2. Select the **Order Group Builder** (Admin > Beacon Admin > Order Group Builder)
3. Create a **new order group** named "IMFINZI for ES-SCLC"
4. Set the default category to **Medications**

Suggested Treatment Plan and Order Set Instructions (cont'd)

Step 1: Create or Update the Order Groups (cont'd)

Order Group 1: IMFINZI for ES-SCLC (cont'd)

5. Add the **details** for IMFINZI to the order group:
   - Right click in the empty field at the bottom of the window
   - Select Add Orders > choose IMFINZI
   - Complete the medication details for IMFINZI. Details may include Sig (instructions), dose, route, frequency, offset time, admin over, and any free-form special admin instructions for the nurse:
     - The recommended dosage of IMFINZI is[1]:
       - Patients with a body weight of ≥30 kg: 1500 mg in combination with chemotherapy* every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks as a single agent
       - Patients with a body weight of <30 kg: 20 mg/kg in combination with chemotherapy* every 3 weeks (21 days) for 4 cycles, followed by 10 mg/kg every 2 weeks as a single agent
     - Until disease progression or unacceptable toxicity[1]
6. Once all the desired information is added, release the Order Group to the production environment after completing testing

*Administer IMFINZI prior to chemotherapy on the same day. Refer to the clinical practice guidelines for the agent administered in combination with IMFINZI for recommended dosage information, as appropriate.

Additional order groups

Add the other desired order groups for IMFINZI (eg, treatment conditions, monitoring and hold parameters, Warnings and Precautions, supportive care, schedulable orders, HCP communications, hydration, and other sections) as desired.

Consider the Prescribing Information below for other order groups:

- There are dosage modifications for adverse reactions. (See the Dosage Modifications section starting on page 5 or Section 2.3 Dosage Modifications of the Prescribing Information)
- For Warnings and Precautions, see Section 5 of the Prescribing Information. Warnings and Precautions:
  - Immune-Mediated Adverse Reactions (5.1)
    - Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, including, but not limited to the following: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated dermatologic adverse reactions, immune-mediated nephritis and renal dysfunction, and solid organ transplant rejection[1]
    - Monitor for early identification and management. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment[1]
    - Withhold or permanently discontinue based on severity and type of reaction[1]

Suggested Treatment Plan and Order Set Instructions (cont'd)

Step 1: Create or Update the Order Groups (cont'd)

Additional order groups (cont'd)

- Infusion-Related Reactions: Interrupt, slow the rate of infusion, or permanently discontinue IMFINZI based on the severity of the reaction. (5.2)[1]
- Complications of Allogeneic HSCT: Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1 blocking antibody. (5.3)[1]
- Embryo-Fetal Toxicity: IMFINZI can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception. (5.4, 8.1, 8.3)[1]

➤ For adverse reactions, see Section 6 of the Prescribing Information. Adverse Reactions:

IMFINZI as a Single Agent

- The most common adverse reactions occurring in ≥20% of patients with LS-SCLC receiving IMFINZI were pneumonitis or radiation pneumonitis (38%), and fatigue (21%).[1]

IMFINZI in Combination with Platinum-Based Chemotherapy

- Most common adverse reactions (≥20% of patients with extensive-stage SCLC) are nausea, fatigue/asthenia, and alopecia (6.1)[1]

Step 2: Add Links for the Prescribing Information and Other Resources

1. Log in to the **Medication Master File (eRx)** with authorized user credentials
2. Use the search feature in the Medication Master File to search for and select IMFINZI
3. Select the **Patient Medication References** screen and create 5 new rows:

Row 1: For Display Name, enter "IMFINZI Prescribing Information."

➤ In the Text field, enter "See URL for additional IMFINZI Prescribing Information."

➤ In the URL field, enter this hyperlink: https://www.azpicentral.com/pi.html?product=imfinzi

Row 2: For Display Name, enter "Provider Support and Resources."

➤ In the Text field, enter "See URL for Support and Resources."

Row 3: For Display Name, enter "Additional resources for Patients and Caregivers."

➤ In the Text field, enter "See URL for additional resources for Patients and Caregivers."

➤ In the URL field, enter this hyperlink: https://www.imfinzi.com/small-cell-lung-cancer/support/patient.html

Suggested Treatment Plan and Order Set Instructions (cont'd)

Step 2: Add Links for the Prescribing Information and Other Resources (cont'd)

Row 5: For Display Name, enter "Dosage and administration details for IMFINZI"

- In the Text field, enter "See URL for dosage and administration details for IMFINZI. See the Dosage and Administration section starting on page 3."
- In the URL field, enter this hyperlink: https://www.azpicentral.com/pi.html?product=imfinzi

Row 6: For Display Name, enter "Clinical Study References for IMFINZI for ES-SCLC: CASPIAN."

- In the Text field, enter "See Section 14, Clinical Study of the IMFINZI Prescribing Information for the CASPIAN clinical study." In the URL field, enter this hyperlink: https://www.azpicentral.com/pi.html?product=imfinzi

Row 7: For Display Name, enter "Clinical Study References for IMFINZI for LS-SCLC: ADRIATIC."

- In the Text field, enter "See Section 14, Clinical Study of the IMFINZI Prescribing Information for the ADRIATIC clinical study." In the URL field, enter this hyperlink: https://www.azpicentral.com/pi.html?product=imfinzi

4. Save the medication record
5. Release the record to the production environment after completing testing

Step 3: Add the Order Groups Created in Step 1 to the New Treatment Plan

1. Click the **Epic logo > Admin > Beacon Admin > Protocol Builder**
2. **Search** for treatment plans using the search query and entering search terms specific to each indication. Note that an existing IMFINZI protocol may be available to optimize. When updating existing plans for IMFINZI, consider updating relevant synonyms to reflect the new indication

   Note: The existing treatment plans will only serve as a template for the new IMFINZI protocol. If the original plan used to create the new IMFINZI protocol includes IMFINZI, confirm it is retired or removed from the EHR production system according to the organization's EHR governing principles
3. In the **Treatment Regimen Calendar:**
   a. **IMFINZI after cCRT for LS-SCLC:** select **28 for the number of days** in each cycle (4-week cycle) until disease progression, unacceptable toxicity, or a maximum of 24 months. Set the Treatment Location as desired
   b. **IMFINZI for 1L ES-SCLC in combination with etoposide and either carboplatin or cisplatin:** select **21 for the number of days** in each cycle (3-week cycle) until disease progression or unacceptable toxicity. For patients with a body weight of ≥30 kg, after the first 4 (21 day) cycles, IMFINZI is administered as a monotherapy every 4 weeks. For patients with a body weight of <30 kg, after the first 4 (21 day) cycles, IMFINZI is administered as a monotherapy every 2 weeks. Set the Treatment Location as desired

Suggested Treatment Plan and Order Set Instructions (cont'd)

Step 3: Add the Order Groups Created in Step 1 to the New Treatment Plan (cont'd)

4. Add all the newly created order groups from Step 1 to the treatment regimen (order groups with IMFINZI, and other order groups) to the treatment calendar and protocol. In the **Calendar**, update and confirm the dosing for IMFINZI:
   a. **IMFINZI after cCRT for LS-SCLC[1]:**
      - Patients with a body weight of ≥30 kg: 1500 mg every 4 weeks
      - Patients with a body weight of <30 kg: 20 mg/kg every 4 weeks
      - Until disease progression, unacceptable toxicity, or a maximum of 24 months.
   b. **IMFINZI for 1L ES-SCLC in combination with etoposide and either carboplatin or cisplatin[1]:**
      - Patients with a body weight of ≥30 kg: 1500 mg in combination with chemotherapy* every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks as a single agent
      - Patients with a body weight of <30 kg: 20 mg/kg in combination with chemotherapy* every 3 weeks (21 days) for 4 cycles, followed by 10 mg/kg every 2 weeks as a single agent
      - Until disease progression or unacceptable toxicity.
5. Update the **treatment plan name for the new treatment plans.** Suggestions are listed below or select another name to align with internal naming conventions:
   a. **IMFINZI after cCRT for LS-SCLC**
   b. **IMFINZI for 1L ES-SCLC in combination with etoposide and either carboplatin or cisplatin**
6. Update the **treatment plan description for the new treatment plans**. Suggestions are listed below or select another name to align with internal naming conventions:
   a. **IMFINZI for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose** disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT)
   b. **IMFINZI in combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)**
7. Update the synonyms for the treatment plan. Consider adding regimen acronyms, generic names, tumor type, location, and other values specific to the treatment plan. Options include:
   a. **IMFINZI for LS-SCLC: LS, SCLC, ADRIATIC**
   b. **IMFINZI for 1L ES-SCLC in combination with etoposide and either carboplatin or cisplatin: ES, SCLC, CASPIAN**
8. Update the Clinical Study Reference for IMFINZI (consider a link to Section 14, Clinical Studies of the IMFINZI Prescribing Information)
9. Click Save
10. **Release** the treatment plan to the production environment after completing testing. To **preference** the new IMFINZI treatment plans, navigate to the protocol selection window and click the star icon before the name of the newly created IMFINZI plan to add both to the Preference list

*Administer IMFINZI prior to chemotherapy on the same day. Refer to clinical practice guidelines for the agent administered in combination with IMFINZI for recommended dosage information, as appropriate.

Please see Important Safety Information on pages 31 to 34 and Full Prescribing Information including Medication Guide for IMFINZI.

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Creating an OurPractice Advisory (OPA) to Identify Certain Adult Patients With Limited-Stage and Extensive-Stage SCLC

Overview and Limitations

- This document is intended to provide health systems with instructions to create an OPA to identify adult patients with limited-stage SCLC whose disease has not progressed following platinum-based cCRT and adult patients with extensive-stage SCLC who are currently using IMFINZI in combination with etoposide and either carboplatin or cisplatin and are candidates for IMFINZI as a single agent in the Epic® EHR system.
- This guide is for the Epic EHR system, and is not appropriate for other conditions, treatments, or therapeutic areas or for other EHR systems.
- The process outlined in this document is variable, and not all steps will apply to every organization. Any steps or settings that are not part of an organization's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The organization is solely responsible for implementing, testing, monitoring, and the ongoing operation of any EHR tools.

Suggested Criteria to Create an OPA to Identify Adult Patients With **Limited-Stage SCLC, Whose Disease Has Not Progressed Following Platinum-based cCRT**

Diagnosis:

- Malignant neoplasm of unspecified part of bronchus or lung (ICD-10: C34.9)[2]

Limited-Stage:

- Any T, any N, M0[3]

Medications:

- Platinum-based chemotherapy[4]

AND

- Etoposide[4]

Procedures:

- Radiation therapy (CPT codes 77300–77399)[4,5]

Note: Review how staging information is entered in the patient chart. AJCC staging SmartForms are available in Epic® to document TNM staging status but may not be routinely and consistently used across the health system. If staging is not available in structured data, consider alternative options and/or a manual chart review to confirm staging status. The instructions leverage the SmartData element to find staging information. Cancer stage rules may be created by the clinical analyst as an alternative.

AJCC=American Joint Committee on Cancer; CPT®=Current Procedural Terminology®; ICD-10=International Classification of Diseases, 10th Revision; TNM=tumor, node, metastases.

Suggested Instructions to Create an OPA to Identify Adult Patients With **Limited-Stage SCLC, Whose Disease Has Not Progressed Following Platinum-based cCRT**

The clinical decision support solution for Epic®, an OPA, may be created to align with the health system's clinical preferences and workflow. An OPA creates awareness for clinical staff.

The first step is to create a procedures group (if not currently available) to bundle the radiation therapy (CPT codes 77300–77399) codes. After the procedure grouper has been created, the criteria and base records for the OurPractice Advisory can be completed to identify patients with limited-stage SCLC whose disease has not progressed following platinum-based cCRT.

Step 1: Create the radiation therapy procedures grouper record

1. Access the Grouper Record Editor in Tools > Management Console
2. Select the Procedure (EAP) master file
3. Add the radiation therapy CPT code range 77300–77399 to the procedure grouper.
4. Click Save

Note: Creating grouper records requires administrative rights. Consult your organization if administrative user rights are required to access the reporting solutions.

Step 2: Create the OPA

Create the OPA criteria records

SCLC diagnosis

1. Navigate to the **Management Console** and click **OurPractice Advisory** in the Decision Support menu (or search for OurPractice)
2. Create a new **Criteria** record and enter a unique name, eg, "C Small-Cell Lung Cancer diagnosis"
3. Select the **Diagnoses** criteria type and select the ICD-10 code for SCLC C34.9
4. Click **Accept**

Limited-stage staging information

1. Navigate to the **Management Console** and click **OurPractice Advisory** in the Decision Support menu (or search for OurPractice)
2. Create a new **Criteria** record and enter a unique name, eg, "C Limited-Stage Staging information"
3. Select the **SmartData Elements** criteria type and select and include the limited-stage staging information (any T, any N, M0)
4. Click **Accept**

Note: A rule record (CER) may be available or created to capture staging information. Consider using this criterion type if desired

CER=clinical evaluation report; EAP=Epic All Procedure.

Suggested Instructions to Create an OPA to Identify Adult Patients With **Limited-Stage SCLC, Whose Disease Has Not Progressed Following Platinum-based cCRT** (cont'd)

Platinum-based chemotherapy

1. Navigate to the **Management Console** and click **OurPractice Advisory** in the Decision Support menu (or search for OurPractice)
2. Create a new **Criteria** record and enter a unique name, eg, "C Platinum-based chemotherapy"
3. Select the **Medications (Include)** criteria type and select and include the platinum-based chemotherapy agents
4. Click **Accept**

Etoposide

1. Navigate to the **Management Console** and click **OurPractice Advisory** in the Decision Support menu (or search for OurPractice)
2. Create a new **Criteria** record and enter a unique name, eg, "C Etoposide"
3. Select the **Medications (Include)** criteria type and select and include etoposide
4. Click **Accept**

Radiation therapy procedures

1. Navigate to the **Management Console** and click **OurPractice Advisory** in the Decision Support menu (or search for OurPractice)
2. Create a new **Criteria** record and enter a unique name, eg, "C Radiation therapy procedures"
3. Select the **Procedures (Include)** criteria type and select and include the **radiation therapy procedures** grouper
4. Click **Accept**

Create the OPA base record

1. Navigate to the Management Console and click **OurPractice Advisory** in the Decision Support menu (or search for OurPractice)
2. Create a Base record with a unique name, eg, "B Limited-Stage SCLC"
3. In the Display section, enter the alert message to display: *"This patient with Limited-Stage SCLC disease has not progressed following platinum-based chemotherapy and radiation therapy (cCRT) and may be a candidate for IMFINZI"*
4. Select **Linked Criteria** from the menu and then select the previously created criteria records (refer to the *Create the OurPractice Advisory Criteria Records* chapter):
   a. Line 1: C Small-Cell Lung Cancer diagnosis
   b. Line 2: C Limited-Stage Staging information
   c. Line 3: C Platinum-based chemotherapy
   d. Line 4: C Etoposide
   e. Line 5: C Radiation therapy procedures

Suggested Instructions to Create an OPA to Identify Adult Patients With **Limited-Stage SCLC, Whose Disease Has Not Progressed Following Platinum-based cCRT** (cont'd)

Create the OPA base record (cont'd)

5. Set the **Logic** for the Criteria Records created previously to 1 AND 2 AND 3 AND 4 AND 5
6. Select the desired **Triggers** to set up the OurPractice Advisory in the workflow
7. Click the **Restrictions** tab to narrow the target audience as desired (medical oncology). In the Encounter Limitation Inclusion grid, set the **Specialty**, **Department**, and **Provider Type** as desired. The selections may vary depending on how the organization was set up in the EHR
8. Set the Action to the desired treatment plan
9. In the **Acknowledge Reason** section, enter any desired acknowledgment reasons
10. Release after satisfactory testing has been completed

Suggested Criteria to Create an OPA to Identify Adult Patients With **Extensive-stage SCLC, Who Are Currently Using IMFINZI in Combination With Etoposide and Either Carboplatin or Cisplatin and Are Candidates for IMFINZI as a Single Agent**

Diagnosis:

- Malignant neoplasm of unspecified part of bronchus or lung (ICD-10: C34.9)[2]

Extensive-stage:

- Any T, any N, M1a[3]
- Any T, any N, M1b[3]
- Any T, any N, M1c[3]

Medications:

- IMFINZI[4]

AND

- Etoposide[4]

AND

- Carboplatin OR cisplatin[4]

Note: Review how staging information is entered in the patient chart. AJCC staging SmartForms are available in Epic® to document TNM staging status but may not be routinely and consistently used across the health system. If staging is not available in structured data, consider alternative options and/or a manual chart review to confirm staging status. The instructions leverage the SmartData element to find staging information. Cancer stage rules may be created by the clinical analyst as an alternative.

Suggested Instructions to Create an OPA to Identify Adult Patients With **Extensive-stage SCLC, Who Are Currently Using IMFINZI in Combination With Etoposide and Either Carboplatin or Cisplatin and Are Candidates for IMFINZI as a Single Agent**

The clinical decision support solution for Epic®, an OPA, may be created to align with the health system's clinical preferences and workflow. An OPA creates awareness for clinical staff.

Create the OPA

Create the OPA criteria records

SCLC diagnosis

1. Navigate to the **Management Console** and click **OurPractice Advisory** in the Decision Support menu (or search for OurPractice)
2. Create a new **Criteria** record and enter a unique name, eg, "C Small-Cell Lung Cancer diagnosis"
3. Select the **Diagnoses** criteria type and select the ICD-10 code for SCLC C34.9
4. Click **Accept**

Extensive-stage staging information

5. Navigate to the **Management Console** and click **OurPractice Advisory** in the Decision Support menu (or search for OurPractice)
6. Create a new **Criteria** record and enter a unique name, eg, "C Extensive-Stage Staging information"
7. Select the **SmartData Elements** criteria type and select and include the Extensive-Stage staging information:
   - Any T, any N, M1a
   - Any T, any N, M1b
   - Any T, any N, M1c
8. Click **Accept**

Note: a rule record (CER) may be available or created to capture staging information. Consider using this criterion type if desired

IMFINZI and etoposide

1. Navigate to the **Management Console** and click **OurPractice Advisory** in the Decision Support menu (or search for OurPractice)
2. Create a new **Criteria** record and enter a unique name, eg, "C IMFINZI and etoposide"
3. Select the **Medications (Include)** criteria type and select and include IMFINZI and etoposide
4. Click **Accept**

Suggested Instructions to Create an OPA to Identify Adult Patients With **Extensive-stage SCLC, Who Are Currently Using IMFINZI in Combination With Etoposide and Either Carboplatin or Cisplatin and Are Candidates for IMFINZI as a Single Agent** (cont'd)

Carboplatin

1. Navigate to the **Management Console** and click **OurPractice Advisory** in the Decision Support menu (or search for OurPractice)
2. Create a new **Criteria** record and enter a unique name, eg, "C Carboplatin"
3. Select the **Medications (Include)** criteria type and select and include carboplatin
4. Click **Accept**

Cisplatin

1. Navigate to the **Management Console** and click **OurPractice Advisory** in the Decision Support menu (or search for OurPractice)
2. Create a new **Criteria** record and enter a unique name, eg, "C Cisplatin"
3. Select the **Medications (Include)** criteria type and select and include cisplatin
4. Click **Accept**

Create the OPA base record

1. Navigate to the **Management Console** and click **OurPractice Advisory** in the Decision Support menu (or search for OurPractice)
2. Create a Base record with a unique name, eg, "B Extensive-Stage SCLC"
3. In the Display section, enter the alert message to display: *"This patient with Extensive-Stage SCLC disease is currently using IMFINZI in combination with etoposide and either carboplatin or cisplatin and may be a candidate for IMFINZI as a single agent"*
4. Select **Linked Criteria** from the menu and then select the previously created criteria records (refer to the *Create the OurPractice Advisory Criteria Records* chapter):
   a. Line 1: C Small-Cell Lung Cancer diagnosis
   b. Line 2: C Extensive-Stage Staging information
   c. Line 3: C IMFINZI and etoposide
   d. Line 4: C Carboplatin
   e. Line 5: C Cisplatin
6. Set the **Logic** for the Criteria records created previously to 1 AND 2 AND 3 AND (4 OR 5)
7. Select the desired **Triggers** to set up the OurPractice Advisory in the workflow

Suggested Instructions to Create an OPA to Identify Adult Patients With **Extensive-stage SCLC, Who Are Currently Using IMFINZI in Combination With Etoposide and Either Carboplatin or Cisplatin and Are Candidates for IMFINZI as a Single Agent** (cont'd)

Create the OPA base record (cont'd)

8. Click the **Restrictions** tab to narrow the target audience as desired (medical oncology). In the Encounter Limitation Inclusion grid, set the **Specialty, Department, and Provider Type** as desired. The selections may vary depending on how the organization was set up in the EHR
9. Set the Action to the desired treatment plan
10. In the **Acknowledge Reason** section, enter any desired acknowledgment reasons
11. Release after satisfactory testing has been completed

Creating a patient list to 1) ID certain adults with LS SCLC and 2) ID certain adults with ES SCLC

Overview and Limitations

- This document is intended to provide health systems with instructions to create a patient list in the Epic® EHR system to identify adult patients with limited-stage SCLC whose disease has not progressed following platinum-based cCRT and adult patients with extensive-stage SCLC who are currently using IMFINZI in combination with etoposide and either carboplatin or cisplatin and are candidates for IMFINZI as a single agent.
- This guide is for the Epic EHR system, and is not appropriate for other conditions, treatments, or therapeutic areas or for other EHR systems.
- The process outlined in this document is variable, and not all steps will apply to every organization. Any steps or settings that are not part of an organization's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The organization is solely responsible for implementing, testing, monitoring, and the ongoing operation of any EHR tools.

Suggested Criteria for Patient List to Identify **Adult Patients With Limited-stage SCLC Whose Disease Has Not Progressed Following Platinum-based cCRT**

Diagnosis:

- Malignant neoplasm of unspecified part of bronchus or lung (ICD-10: C34.9)[2]

Limited-Stage:

- Any T, any N, M0[3]

Medications:

- Platinum-based chemotherapy[4]

AND

- Etoposide[4]

Procedures:

- Radiation therapy (CPT codes 77300–77399)[4,5]

Suggested Criteria for Patient List to Identify **Adult Patients With Extensive-stage SCLC, Who Are Currently Using IMFINZI in Combination With Etoposide and Either Carboplatin or Cisplatin and Are Candidates for IMFINZI as a Single Agent**

Diagnosis:

- Malignant neoplasm of unspecified part of bronchus or lung (ICD-10: C34.9)[2]

Extensive-stage:

- Any T, any N, M1a[3]
- Any T, any N, M1b[3]
- Any T, any N, M1c[3]

Medications:

- IMFINZI[4]

AND

- Etoposide[4]

AND

- Carboplatin OR cisplatin[4]

Note: Consider running the report on a regular basis. Once the initial report has been created, it can be saved for future use and subsequent reports can be re-run. Running reports over time allow to identify new patients meeting the inclusion criteria.

Suggested Instructions to Identify **Adult Patients With Limited-stage SCLC Whose Disease Has Not Progressed Following Platinum-based cCRT** and **Adult Patients With Extensive-stage SCLC Who Are Currently Using IMFINZI in Combination With Etoposide and Either Carboplatin or Cisplatin and are Candidates for IMFINZI as a Single Agent**

Consider Reporting Workbench or SlicerDicer to create the patient list. Consult your organization if administrative user rights are required to access the reporting solutions.

Review documentation practices in the EHR when considering creating the patient report. Two options are provided in the instructions: Reporting Workbench and SlicerDicer. Depending on availability, consider the preferred reporting tool to complete the patient report. SlicerDicer may not always include a SmartData or Staging search criterion.

The steps below detail the steps to create two patient lists:

1. **Adult patients with limited-stage SCLC whose disease has not progressed following platinum-based cCRT**
2. **Adult patients with extensive-stage SCLC who are currently using IMFINZI in combination with etoposide and either carboplatin or cisplatin and are candidates for IMFINZI as a single agent**

Note: Review how staging information is entered in the patient chart. AJCC staging SmartForms are available in Epic® to document TNM staging status but may not be routinely and consistently used across the health system. If staging is not available in structured data, consider alternative options and/or a manual chart review to confirm staging status. The instructions leverage the SmartData element to find staging information. Cancer stage rules may be created by the clinical analyst as an alternative.

Option 1: Reporting Workbench – Using the Generic Criteria Report Template

Both patient lists start with these set of steps in Reporting Workbench

1. Access Reporting Workbench (click the Epic logo > Reports > My Reports).
2. Navigate to the Library tab from the Reports menu.
3. Enter “generic criteria” in the search field and click Search.
4. Select the Find Patients - Generic Criteria report and click New.
5. In the Report Settings window, select the Criteria tab and add the first criterion to the query.
6. In the Find Criteria search field, enter “living” and select the Patient Living Status and set the status to Alive.
7. In the Find Criteria field, enter “diagnosis” and select the Diagnosis by Code criterion
8. Enter and select the small-cell lung cancer ICD-10 code C34.9.

Suggested Instructions to Identify Adult Patients With Limited-stage SCLC Whose Disease Has Not Progressed Following Platinum-based cCRT and **Adult Patients With Extensive-stage SCLC Who Are Currently Using IMFINZI in Combination With Etoposide and Either Carboplatin or Cisplatin and are Candidates for IMFINZI as a Single Agent** (cont'd)

Option 1: Reporting Workbench – Using the Generic Criteria Report Template (cont'd)

9A. **In the Find Criteria field, enter "SmartData" and select the SmartData element criterion**

a. **Certain patients with extensive-stage SCLC:** Enter and select the extensive-stage SCLC cancer status elements: any T, any N, M1a, M1b and M1c (consider entering search terms AJCC, Staging, or TNM Classification to find the desired SmartData element)

10A. **In the Find Criteria search field, enter "medications" and...**

a. **Certain patients with extensive-stage SCLC:** In the Find Criteria search field, enter "medications" and select the Meds: "All time (by exact medication)" criterion. Enter and select IMFINZI and etoposide and select all formulations.

b. **Certain patients with extensive-stage SCLC:** In the Find Criteria search field, enter "medications" and select "the Meds: All time (by exact medication)" criterion. Enter and select carboplatin and cisplatin and select all formulations. Set the criterion logic in this criterion to "OR".

11A. **In the Find Criteria search field, enter "procedures" and select the Procedures criterion**.

a. **Certain patients with extensive-stage SCLC:** not needed.

12A. **Setting the logic:**

a. **Certain patients with extensive-stage SCLC:** Set the logic to include the patient living status, diagnosis, extensive-stage status and medications.

13A. Select the Display tab to set all display columns for the report. Search for any display information in the Available Columns pane. Select all desired columns and click the right arrow to drag to the Selected Columns pane.

Suggested Instructions to Identify **Adult Patients With Limited-stage SCLC Whose Disease Has Not Progressed Following Platinum-based cCRT** and Adult Patients With Extensive-stage SCLC Who Are Currently Using IMFINZI in Combination With Etoposide and Either Carboplatin or Cisplatin and are Candidates for IMFINZI as a Single Agent (cont'd)

Option 1: Reporting Workbench – Using the Generic Criteria Report Template (cont'd)

9B. **In the Find Criteria field, enter "SmartData" and select the SmartData element criterion**

a. **Certain patients with limited-stage SCLC:** Enter and select the limited-stage SCLC cancer status elements: any T, any N, M0 (consider entering search terms AJCC, Staging or TNM Classification to find the desired SmartData element)

10B. **In the Find Criteria search field, enter "medications" and...**

a. **Certain patients with limited-stage SCLC:** select the "Meds: All time (by simple generic name)" criterion. Enter and select the platinum-based chemotherapy medications and etoposide.

11B. **In the Find Criteria search field, enter "procedures" and select the Procedures criterion**.

a. **Certain patients with limited-stage SCLC:** Enter and select the radiation therapy CPT code range 77300–77399.

12B. **Setting the logic:**

a. **Certain patients with limited-stage SCLC:** Set the logic to include the patient living status, diagnosis, limited-stage status, medications, and procedures.

13B. Select the Display tab to set all display columns for the report. Search for any display information in the Available Columns pane. Select all desired columns and click the right arrow to drag to the Selected Columns pane.

Suggested Instructions to Identify **Adult Patients With Limited-stage SCLC Whose Disease Has Not Progressed Following Platinum-based cCRT** and **Adult Patients With Extensive-stage SCLC Who Are Currently Using IMFINZI in Combination With Etoposide and Either Carboplatin or Cisplatin and are Candidates for IMFINZI as a Single Agent** (cont'd)

Option 1: Reporting Workbench – Using the Generic Criteria Report Template (cont'd)

14. In the Display tab, navigate to the Detailed Views section and set additional information displays. Consider adding the current and past medications, springboard and cancer stage summary views.
15. In the General tab, enter the desired Report Name (for example **"Limited-Stage SCLC"** or **"Extensive-Stage SCLC"**) and a Description. Results can be shared with selected users or pools.
16. Click Save and Run to create the patient list. The list will display all patients matching the criteria.

Option 2: SlicerDicer

1. Access SlicerDicer (click the Epic logo > Reports > SlicerDicer).
2. Depending on availability, select the Patients or Patients with Cancer data model (the number in the data model box represent the base population and number of records in the data model).
3. In the right-hand column, select the desired patient base, for example All Patients (Note: First time users of SlicerDicer may see a tutorial prompted during initial use. Complete the tutorial and continue with the steps described in this resource).
4. In the Search for criteria field, enter status. Alternatively, the + Browse button can be used too. When using the + Browse button, a new screen will display where the filter criterion and inclusion/exclusion status can be selected.
5. Select the Patient Living Status criterion and set to Alive.
6. In the Search for criteria field, enter diagnosis.
7. Select the Diagnosis criteria.
8. Set the mode to ICD/Grouper and enter the small-cell lung cancer ICD-10 code C34.9.
9. In the Search for criteria field, enter SmartData (or stage, depending on the configuration of the data model. Note, if this criterion is not available, complete the steps below, and export the slice to Reporting Workbench to add the staging criterion).

Suggested Instructions to Identify **Adult Patients With Limited-stage SCLC Whose Disease Has Not Progressed Following Platinum-based cCRT** and Adult Patients With Extensive-stage SCLC Who Are Currently Using IMFINZI in Combination With Etoposide and Either Carboplatin or Cisplatin and are Candidates for IMFINZI as a Single Agent (cont'd)

Option 2: SlicerDicer (cont'd)

10A. Select the SmartData or Stage criteria.

a. **Certain patients with limited-stage SCLC:** Enter and select the extensive-stage SCLC cancer status elements: any T, any N, M0 (consider entering search terms AJCC, Staging, or TNM Classification to find the desired SmartData element)

11B. In the Search for criteria field, enter medication.

a. **Certain patients with limited-stage SCLC:** Enter and select the platinum-based chemotherapy medications and etoposide

12B. In the Search for criteria field, enter procedures.

a. **Certain patients with limited-stage SCLC:** Enter and select the radiation therapy CPT code range 77300–77399

13B. **Setting the logic:**

a. **Certain patients with limited-stage SCLC:** Set the logic to include the patient living status, diagnosis, limited-stage status, medications, and procedures.

14A. Click the last icon with the detail table in the Visual Option section to see the query results.

15A. The results can be exported to Reporting Workbench by right clicking the bar with the patient results and selecting Show Slice in Reporting Workbench.

16A. In Reporting workbench, select the Display tab to set all display columns for the report. Search for any display information in the Available Columns pane. Select all desired columns and click the right arrow to drag to the Selected Columns pane.

17A. In the Display tab, navigate to the Detailed Views section and set additional information displays. Consider adding the current and past medications, springboard and cancer stage summary views.

18A. In the General tab, enter the desired Report Name (eg, "Limited-Stage SCLC") and a Description. Results can be shared with selected users or pools.

19A. Click Save and Run to create the patient list. The list will display all patients matching the criteria.

Suggested Instructions to Identify **Adult Patients With Limited-stage SCLC Whose Disease Has Not Progressed Following Platinum-based cCRT** and **Adult Patients With Extensive-stage SCLC Who Are Currently Using IMFINZI in Combination With Etoposide and Either Carboplatin or Cisplatin and are Candidates for IMFINZI as a Single Agent** (cont'd)

Option 2: SlicerDicer (cont'd)

10B. Select the SmartData or Stage criteria.

a. **Certain patients with extensive-stage SCLC:** Enter and select the extensive-stage SCLC cancer status elements: any T, any N, M1a, M1b and M1c (consider entering search terms AJCC, Staging, or TNM Classification to find the desired SmartData element)

11B. In the Search for criteria field, enter medication.

a. **Certain patients with extensive-stage SCLC:** Enter and select IMFINZI and etoposide and select all formulations.

b. **Certain patients with extensive-stage SCLC:** Enter and select carboplatin and cisplatin and select all formulations. Set the criterion logic in this criterion to OR.

12B. In the Search for criteria field, enter procedures.

a. **Certain patients with extensive-stage SCLC:** not needed.

13B. **Setting the logic:**

a. **Certain patients with extensive-stage SCLC:** Set the logic to include the patient living status, diagnosis, extensive-stage status and medications.

14B. Click the last icon with the detailed table in the Visual Option section to see the query results.

15B. The results can be exported to Reporting Workbench by right clicking the bar with the patient results and selecting Show Slice in Reporting Workbench.

16B. In Reporting workbench, select the Display tab to set all display columns for the report. Search for any display information in the Available Columns pane. Select all desired columns and click the right arrow to drag to the Selected Columns pane.

17B. In the Display tab, navigate to the Detailed Views section and set additional information displays. Consider adding the current and past medications, springboard and cancer stage summary views.

18B. In the General tab, enter the desired Report Name (eg, "Limited-Stage SCLC") and a Description. Results can be shared with selected users or pools.

19B. Click Save and Run to create the patient list. The list will display all patients matching the criteria.

Notes

- The customer (eg, physician, medical group, integrated delivery network) shall be solely responsible for the implementation, testing, and monitoring of the instructions to ensure proper orientation in each customer's EHR system
- Capabilities, functionality, and setup (customization) for each EHR system may vary. AstraZeneca shall not be responsible for revising the implementation instructions it provides to any customer if the customer modifies or changes its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by AstraZeneca
- While AstraZeneca tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems, and AstraZeneca shall have no liability thereto
- While EHRs may assist providers in identifying appropriate patients for consideration of assessment, treatment, and referral, the decision and action should ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility, and AstraZeneca shall have no liability thereto
- The instructions have not been designed for, and are not tools and/or solutions for, meeting Advancing Care Information and/or any other quality/accreditation requirement
-

Indications and Important Safety Information

Indication:

- IMFINZI, as a single agent, is indicated for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT).
- IMFINZI, in combination with etoposide and either carboplatin or cisplatin, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

IMPORTANT SAFETY INFORMATION

There are no contraindications for IMFINZI® (durvalumab).

Immune-Mediated Adverse Reactions

Important immune-mediated adverse reactions listed under Warnings and Precautions may not include all possible severe and fatal immune-mediated reactions. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting treatment or after discontinuation. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate. Withhold or permanently discontinue IMFINZI depending on severity. See USPI Dosing and Administration for specific details. In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

Immune-Mediated Pneumonitis

IMFINZI can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation. In patients who did not receive recent prior radiation, the incidence of immune-mediated pneumonitis was 2.4% (34/1414), including fatal (<0.1%), and Grade 3-4 (0.4%) adverse reactions The incidence of pneumonitis (including radiation pneumonitis) in patients with LS-SCLC following chemoradiation within 42 days prior to initiation of IMFINZI in ADRIATIC was 14% (37/262) in patients receiving IMFINZI and 6% (16/265) in patients receiving placebo. Of the patients who received IMFINZI (262), 0.4% had a fatal adverse reaction and 2.7% had Grade 3 adverse reactions. The frequency and severity of immune-mediated pneumonitis in patients who did not receive definitive chemoradiation prior to IMFINZI were similar in patients who received IMFINZI as a single agent or with ES-SCLC or BTC when given in combination with chemotherapy.

Immune-Mediated Colitis

IMFINZI can cause immune-mediated colitis that is frequently associated with diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies. Immune-mediated colitis occurred in 2% (37/1889) of patients receiving IMFINZI, including Grade 4 (<0.1%) and Grade 3 (0.4%) adverse reactions.

Please see the accompanying Full Prescribing Information including Medication Guide for IMFINZI.

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Important Safety Information (cont'd)

Immune-Mediated Hepatitis

IMFINZI can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 2.8% (52/1889) of patients receiving IMFINZI, including fatal (0.2%), Grade 4 (0.3%) and Grade 3 (1.4%) adverse reactions.

Immune-Mediated Endocrinopathies

- ***Adrenal Insufficiency:*** IMFINZI can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Immune-mediated adrenal insufficiency occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
- ***Hypophysitis:*** IMFINZI can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate symptomatic treatment including hormone replacement as clinically indicated. Grade 3 hypophysitis/hypopituitarism occurred in <0.1% (1/1889) of patients who received IMFINZI.
- ***Thyroid Disorders:*** IMFINZI can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement therapy for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated.
  - ***Thyroiditis:*** Immune-mediated thyroiditis occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
  - ***Hyperthyroidism:*** Immune-mediated hyperthyroidism occurred in 2.1% (39/1889) of patients receiving IMFINZI.
  - ***Hypothyroidism:*** Immune-mediated hypothyroidism occurred in 8.3% (156/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
- ***Type 1 Diabetes Mellitus, which can present with diabetic ketoacidosis:*** Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Grade 3 immune-mediated Type 1 diabetes mellitus occurred in <0.1% (1/1889) of patients receiving IMFINZI.

Immune-Mediated Nephritis with Renal Dysfunction

IMFINZI can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 0.5% (10/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.

Immune-Mediated Dermatology Reactions

IMFINZI can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson Syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN), has occurred with PD-1/L-1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Immune-mediated rash or dermatitis occurred in 1.8% (34/1889) of patients receiving IMFINZI, including Grade 3 (0.4%) adverse reactions.

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IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Important Safety Information (cont'd)

Other Immune-Mediated Adverse Reactions

The following clinically significant, immune-mediated adverse reactions occurred at an incidence of less than 1% each in patients who received IMFINZI or were reported with the use of other PD-1/PD-L1 blocking antibodies.

- ***Cardiac/vascular:*** Myocarditis, pericarditis, vasculitis.
- ***Nervous system:*** Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy.
- ***Ocular:*** Uveitis, iritis, and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.
- ***Gastrointestinal:*** Pancreatitis including increases in serum amylase and lipase levels, gastritis, duodenitis.
- ***Musculoskeletal and connective tissue disorders:*** Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatic.
- ***Endocrine:*** Hypoparathyroidism.
- ***Other (hematologic/immune):*** Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Infusion-Related Reactions

IMFINZI can cause severe or life-threatening infusion-related reactions. Monitor for signs and symptoms of infusion-related reactions. Interrupt, slow the rate of, or permanently discontinue IMFINZI based on the severity. See USPI Dosing and Administration for specific details. For Grade 1 or 2 infusion-related reactions, consider using pre-medications with subsequent doses. Infusion-related reactions occurred in 2.2% (42/1889) of patients receiving IMFINZI, including Grade 3 (0.3%) adverse reactions.

Complications of Allogeneic HSCT after IMFINZI

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/L-1 blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/L-1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/L-1 blocking antibody prior to or after an allogeneic HSCT.

Please see the accompanying Full Prescribing Information including Medication Guide for IMFINZI.

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durvalumab
Injection for Intravenous Use 50 mg/mL

Important Safety Information (cont'd)

Embryo-Fetal Toxicity

Based on its mechanism of action and data from animal studies, IMFINZI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. In females of reproductive potential, verify pregnancy status prior to initiating IMFINZI and advise them to use effective contraception during treatment with IMFINZI and for 3 months after the last dose of IMFINZI.

Lactation

There is no information regarding the presence of IMFINZI in human milk; however, because of the potential for adverse reactions in breastfed infants from IMFINZI, advise women not to breastfeed during treatment and for 3 months after the last dose.

Adverse Reactions

- In patients with limited-stage SCLC in the ADRIATIC study receiving IMFINZI (n=262), the most common adverse reactions occurring in ≥20% of patients receiving IMFINZI were pneumonitis or radiation pneumonitis (38%), and fatigue (21%). The most common Grade 3 or 4 adverse reactions (≥3%) were pneumonitis or radiation pneumonitis and pneumonia.
- In patients with limited-stage SCLC in the ADRIATIC study receiving IMFINZI (n=262), IMFINZI was permanent discontinued due to adverse reactions in 16% of the patients receiving IMFINZI. Serious adverse reactions occurred in 30% of patients receiving IMFINZI. The most frequent serious adverse reactions reported in ≥1% of patients receiving IMFINZI were pneumonitis or radiation pneumonitis (12%), and pneumonia (5%). Fatal adverse reactions occurred in 2.7% of patients who received IMFINZI including pneumonia (1.5%), cardiac failure, encephalopathy and pneumonitis (0.4% each).
- In patients with extensive-stage SCLC in the CASPIAN study receiving IMFINZI plus chemotherapy (n=265), the most common adverse reactions (≥20%) were nausea (34%), fatigue/asthenia (32%), and alopecia (31%). The most common Grade 3 or 4 adverse reactions (≥3%) was fatigue/asthenia (3.4%).
- In patients with extensive-stage SCLC in the CASPIAN study receiving IMFINZI plus chemotherapy (n=265), IMFINZI was discontinued due to adverse reactions in 7% of the patients receiving IMFINZI plus chemotherapy. Serious adverse reactions occurred in 31% of patients receiving IMFINZI plus chemotherapy. The most frequent serious adverse reactions reported in at least 1% of patients were febrile neutropenia (4.5%), pneumonia (2.3%), anemia (1.9%), pancytopenia (1.5%), pneumonitis (1.1%), and COPD (1.1%). Fatal adverse reactions occurred in 4.9% of patients receiving IMFINZI plus chemotherapy.

The safety and effectiveness of IMFINZI has not been established in pediatric patients.

Please see the accompanying Full Prescribing Information including Medication Guide for IMFINZI.

References: 1. IMFINZI® (durvalumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2024. **2.** 2025 ICD-10-CM Diagnosis Code C34.9. Accessed September 23, 2024. https://www.icd10data.com/ICD10CM/Codes/C00-D49/C30-C39/C34-/C34.9 **3.** Cancer Research UK. Limited and extensive stage (small cell lung cancer). January 04, 2023. Accessed December 13, 2024. https://www.cancerresearchuk.org/about-cancer/lung-cancer/stages-types-grades/limited-extensive **4.** National Cancer Institute. Small cell lung cancer treatment (PDQ®)–Health Professional Version. June 27, 2024. Accessed December 13, 2014. https://www.cancer.gov/types/lung/hp/small-cell-lung-treatment-pdq **5.** eviCore Healthcare. Cigna radiation oncology coding manual. April 10, 2024. Accessed November 22, 2024. https://www.evicore.com/sites/default/files/clinical-guidelines/2024-04/Cigna_Radiation% 20Oncology%20Coding%20Manual_V2.0.2022_eff04.10.2024_pub04.10.2024.pdf

AstraZeneca

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL