Ordering COSENTYX® in EHR Systems

Cosentyx® (secukinumab)

Order Set and Therapy Plan Configuration Examples

BACKGROUND, INSTRUCTIONS, AND LIMITATIONS

The following instructions have been created by Novartis Pharmaceuticals Corporation to understand how order sets and therapy plans will appear within an outpatient electronic health record (EHR) system. Order sets and therapy plans can improve the user experience. The order sets and therapy plans that appear will vary based on the indication and formulation of COSENTYX. When ordering COSENTYX within an outpatient EHR system, order sets are used for the subcutaneous formulation and therapy plans are used for the intravenous (IV) formulation. These instructions will not work for other conditions, treatments, or therapeutic areas.

The information outlined in this piece is variable, and not all order sets and therapy plans will appear the same way in every outpatient EHR system. Any questions should be directed to the appropriate service provider.

INDICATIONS

COSENTYX® (secukinumab) is indicated for the treatment of moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy.

COSENTYX is indicated for the treatment of active psoriatic arthritis (PsA) in patients 2 years of age and older.

COSENTYX is indicated for the treatment of adult patients with active ankylosing spondylitis (AS).

COSENTYX is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

COSENTYX is indicated for the treatment of active enthesitis-related arthritis (ERA) in patients 4 years of age and older.

COSENTYX is indicated for the treatment of adult patients with moderate to severe hidradenitis suppurativa (HS).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients in COSENTYX. Cases of anaphylaxis and angioedema have been reported during treatment with COSENTYX.

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For more information on how the Novartis Health Information Technology (HIT) Team can collaborate with your organization to identify shared priorities, please email HIT.Novartis@novartis.com.

Please see additional Important Safety Information on pages 5 and 6.
Please see full Prescribing Information, including Medication Guide.

Cosentyx® (secukinumab)

OVERVIEW

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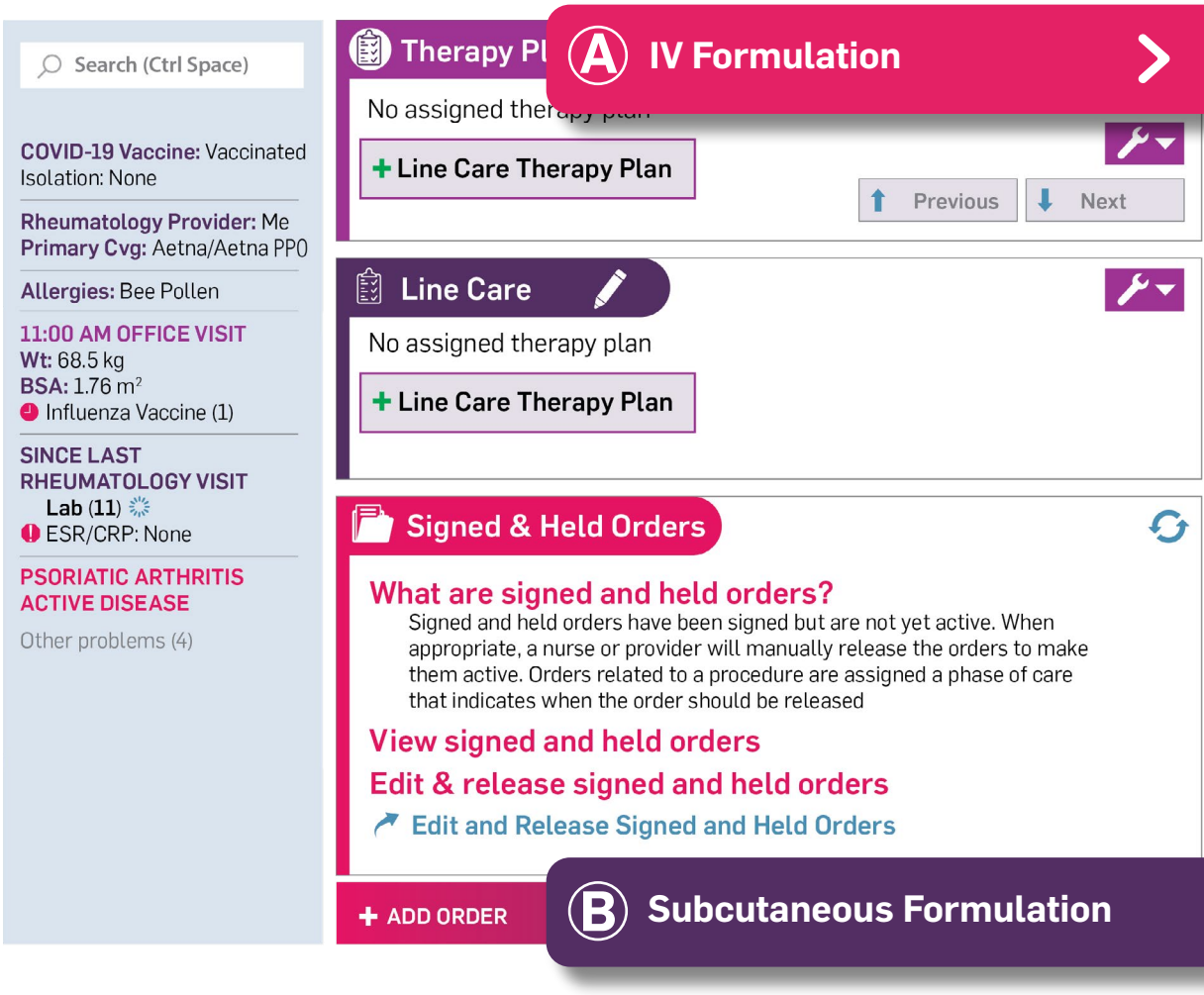
The way you order COSENTYX® within an EHR system depends on which formulation is needed. Within the visit navigator, you can determine whether to add an order set or therapy plan for COSENTYX based on the method of administration. In this piece, we will illustrate what an order set and therapy plan may look like within your EHR system.

A **Therapy plans** are used when ordering the **IV formulation** of COSENTYX

B **Order sets** are used when ordering the **subcutaneous formulation** of COSENTYX



Ordering the Subcutaneous Formulation of COSENTYX® Using Order Sets

Cosentyx® (secukinumab)

SUBCUTANEOUS FORMULATION

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An **order set** is a group of standard orderable items based on condition, disease, or procedure. Order sets may contain orders, documentation, diagnosis, length of stay charges, and/or follow-up instructions.

When using an order set for the subcutaneous formulation of COSENTYX, you will need to search for COSENTYX. After you select COSENTYX, the order set window will show a list of all the **indications of COSENTYX that are subcutaneously administered**.

Indications of COSENTYX for Subcutaneous Administration

COSENTYX Order Set

▼ Diagnosis

- ▶ **Plaque Psoriasis – L40.0**
  Moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy
- ▶ **Psoriatic Arthritis – L40.5***
  Active psoriatic arthritis (PsA) in patients 2 years of age and older
- ▶ **Ankylosing Spondylitis – M45***
  Adult patients with active ankylosing spondylitis (AS)
- ▶ **Non-Radiographic Axial Spondyloarthritis – M45.A***
  Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- ▶ **Enthesitis-Related Arthritis – L40.54 or M08.90**
  Active enthesitis-related arthritis (ERA) in patients 4 years of age and older
- ▶ **Hidradenitis Suppurativa - L73.2**
  Adult patients with moderate to severe hidradenitis suppurativa (HS)

*Indicates to account for any subcodes or child codes underneath the parent code (ie, L40.1, L40.2, etc).

Once you **click on the above appropriate indication**, the order set screen will show all the **detailed dosing and administration** information you'll need.

If the order set window within your EHR system looks different from what is shown here, reach out to your internal IT help desk.

Ordering the Subcutaneous Formulation of COSENTYX® Using Order Sets

Cosentyx® (secukinumab)

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SUBCUTANEOUS FORMULATION

Plaque Psoriasis Example

COSENTYX Order Set

▼ **Diagnosis**

▼ **Plaque Psoriasis**

Moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy

▼ **Medications**

○ Adult patients with PsO

- **Loading dose:** COSENTYX 300 mg once a week for 4 weeks (Weeks 0, 1, 2, and 3)
- **Maintenance dose** (includes Week 4 of loading dose): COSENTYX 300 mg every 4 weeks
  - For some patients a loading and maintenance dose of 150 mg may be acceptable
  - Each 300 mg dosage is given as one subcutaneous injection of 300 mg (300-mg UnoReady® pen) or as two subcutaneous injections of 150 mg (150-mg Sensoready® pen or 150-mg prefilled syringe)

○ Pediatric patients 6 years of age and older with PsO

- **Loading dose:** COSENTYX 75 mg or 150 mg once a week for 4 weeks (Weeks 0, 1, 2, and 3)
- **Maintenance dose** (includes Week 4 of loading dose): COSENTYX 75 or 150 mg every 4 weeks
- The recommended dosage for pediatric patients 6 years and older is based on body weight at time of dosing:
  - For pediatric patients <50 kg, the dose is 75 mg (75-mg prefilled syringe)
  - For pediatric patients ≥50 kg, the dose is 150 mg (150-mg Sensoready pen or 150-mg prefilled syringe)

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Ordering the Subcutaneous Formulation of COSENTYX® Using Order Sets

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SUBCUTANEOUS FORMULATION

Psoriatic Arthritis Example

COSENTYX Order Set

▼ **Diagnosis**

▼ **Psoriatic Arthritis**

Active psoriatic arthritis (PsA) in patients 2 years of age and older

▼ **Medications**

○ Adult patients with PsA and with coexistent moderate to severe plaque psoriasis

- **Loading dose:** COSENTYX 300 mg once a week for 4 weeks (Weeks 0, 1, 2, and 3)
- **Maintenance dose** (includes Week 4 of loading dose): COSENTYX 300 mg every 4 weeks
  - For some patients a loading and maintenance dose of 150 mg may be acceptable
  - Each 300 mg dosage is given as one subcutaneous injection of 300 mg (300-mg UnoReady® pen) or as two subcutaneous injections of 150 mg (150-mg Sensoready® pen or 150-mg prefilled syringe)

○ Other adult patients with PsA

- **Loading dose:** COSENTYX 150 mg once a week for 4 weeks (Weeks 0, 1, 2, and 3); if appropriate
- **Maintenance dose** (includes Week 4 of loading dose): COSENTYX 150 mg every 4 weeks. If a patient continues to have active PsA, consider a dosage of 300 mg
  - COSENTYX 150 mg dosage is administered using a 150-mg Sensoready pen or a 150-mg prefilled syringe
  - Each 300 mg dosage is given as one subcutaneous injection of 300 mg (300-mg UnoReady pen) or as two subcutaneous injections of 150 mg

○ Pediatric patients 2 years of age and older with juvenile psoriatic arthritis (JPsA)

- **Loading dose:** COSENTYX 75 mg or 150 mg once a week for 4 weeks (Weeks 0, 1, 2, and 3)
- **Maintenance dose** (includes Week 4 of loading dose): COSENTYX 75 or 150 mg every 4 weeks
- The recommended dosage for pediatric patients 2 years and older with active PsA is based on body weight at time of dosing
  - For pediatric patients ≥15 kg and <50 kg, the dose is 75 mg (75-mg prefilled syringe)
  - For patients ≥50 kg, the dose is 150 mg (150-mg Sensoready pen or 150-mg prefilled syringe)

Reach out to your internal IT help desk.

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SUBCUTANEOUS FORMULATION

Ankylosing Spondylitis Example

COSENTYX Order Set

- **Diagnosis**
  - **Ankylosing Spondylitis**
    Adult patients with active ankylosing spondylitis (AS)
  - **Medications**
    - **Loading dose:** COSENTYX 150 mg once a week for 4 weeks (Weeks 0, 1, 2, and 3), if appropriate
    - **Maintenance dose** (includes Week 4 of loading dose): COSENTYX 150 mg every 4 weeks. If a patient continues to have active AS, consider a dosage of 300 mg
      - COSENTYX 150 mg dosage is administered using a 150-mg Sensoready® pen or a 150-mg prefilled syringe
      - Each 300 mg dosage is given as one subcutaneous injection of 300 mg (300-mg UnoReady® pen) or as two subcutaneous injections of 150 mg

Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation

- **Enthesitis-Related Arthritis – L40.54 or M08.90**
  Active enthesitis-related arthritis (ERA) in patients 4 years of age and older
- **Hidradenitis Suppurativa - L73.2**
  Adult patients with moderate to severe hidradenitis suppurativa (HS)

*Indicates to account for any subcodes or child codes underneath the parent code (ie, L40.1, L40.2, etc).

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Ordering the Subcutaneous Formulation of COSENTYX® Using Order Sets

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SUBCUTANEOUS FORMULATION

Non-Radiographic Axial Spondyloarthritis Example

COSENTYX Order Set

- **Diagnosis**
  - **Non-Radiographic Axial Spondyloarthritis**
    Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
  - **Medications**
    - **Loading dose:** COSENTYX 150 mg once a week for 4 weeks (Weeks 0, 1, 2, and 3), if appropriate
    - **Maintenance dose** (includes Week 4 of loading dose): COSENTYX 150 mg every 4 weeks.
      - COSENTYX 150 mg dosage is administered using a 150-mg Sensoready® pen or a 150-mg prefilled syringe

Adult patients with active ankylosing spondylitis (AS)

- **Non-Radiographic Axial Spondyloarthritis – M45.A***
  Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- **Enthesitis-Related Arthritis – L40.54 or M08.90**
  Active enthesitis-related arthritis (ERA) in patients 4 years of age and older
- **Hidradenitis Suppurativa - L73.2**
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SUBCUTANEOUS FORMULATION

Enthesitis-Related Arthritis Example

COSENTYX Order Set

- **Diagnosis**
  - **Enthesitis-Related Arthritis**
    Active enthesitis-related arthritis (ERA) in patients 4 years of age and older
  - **Medications**
    - **Loading dose:** COSENTYX 75 mg or 150 mg once a week for 4 weeks (Weeks 0, 1, 2, and 3)
    - **Maintenance dose:** COSENTYX 75 or 150 mg every 4 weeks
      - The recommended dosage for pediatric patients 4 years and older with ERA is based on body weight at time of dosing
        - For pediatric patients ≥15 kg and <50 kg, the dose is 75 mg (75-mg prefilled syringe)
        - For patients ≥50 kg, the dose is 150 mg (150-mg Sensoready® pen or 150-mg prefilled syringe)

- **Non-Radiographic Axial Spondyloarthritis – M45.A***
  Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- **Enthesitis-Related Arthritis – L40.54 or M08.90**
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SUBCUTANEOUS FORMULATION

Hidradenitis Suppurativa Example

COSENTYX Order Set

- **Diagnosis**
  - **Hidradenitis Suppurativa**
    Adult patients with moderate to severe hidradenitis suppurativa (HS)
  - **Medications**
    - **Loading dose:** COSENTYX 300 mg once a week for 4 weeks (Weeks 0, 1, 2, and 3)
    - **Maintenance dose:** (includes Week 4 of loading dose): COSENTYX 300 mg every 4 weeks.
      If a patient does not adequately respond, consider a dosage of 300 mg every 2 weeks
      - Each 300 mg dosage is given as one subcutaneous injection of 300 mg (300-mg UnoReady® pen) or as two subcutaneous injections of 150 mg (150-mg Sensoready® pen or 150-mg prefilled syringe)

Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation

Enthesitis-Related Arthritis – L40.54 or M08.90
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Ordering the IV Formulation of COSENTYX® Using Therapy Plans

Cosentyx® (secukinumab)

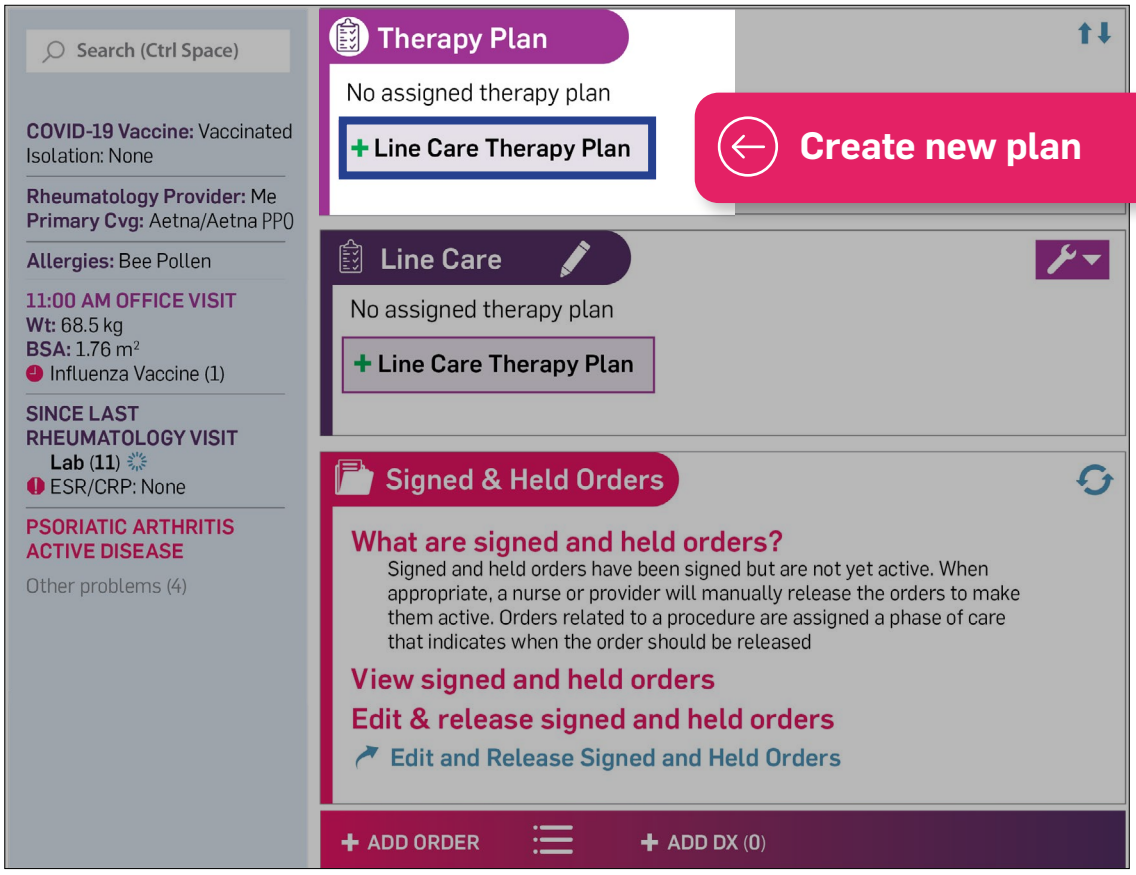
Therapy plans consist of specific sets of orders (eg, medications, labs, imaging, etc) that are administered during scheduled appointments.

A therapy plan includes predefined sets of orders a patient may need (eg, scheduled infusion appointments, labs, nurse orders, and follow-up instructions). These orders can be signed and held and then released by the nurse or provider to make them active.

IV FORMULATION

NEXT >

Navigate to the "**Therapy Plan**" tab and create a new plan by searching for COSENTYX



If the therapy plan window within your EHR system look different from what is shown on the next few pages, reach out to your internal IT help desk.

Ordering the IV Formulation of COSENTYX® Using Therapy Plans

Cosentyx® (secukinumab)

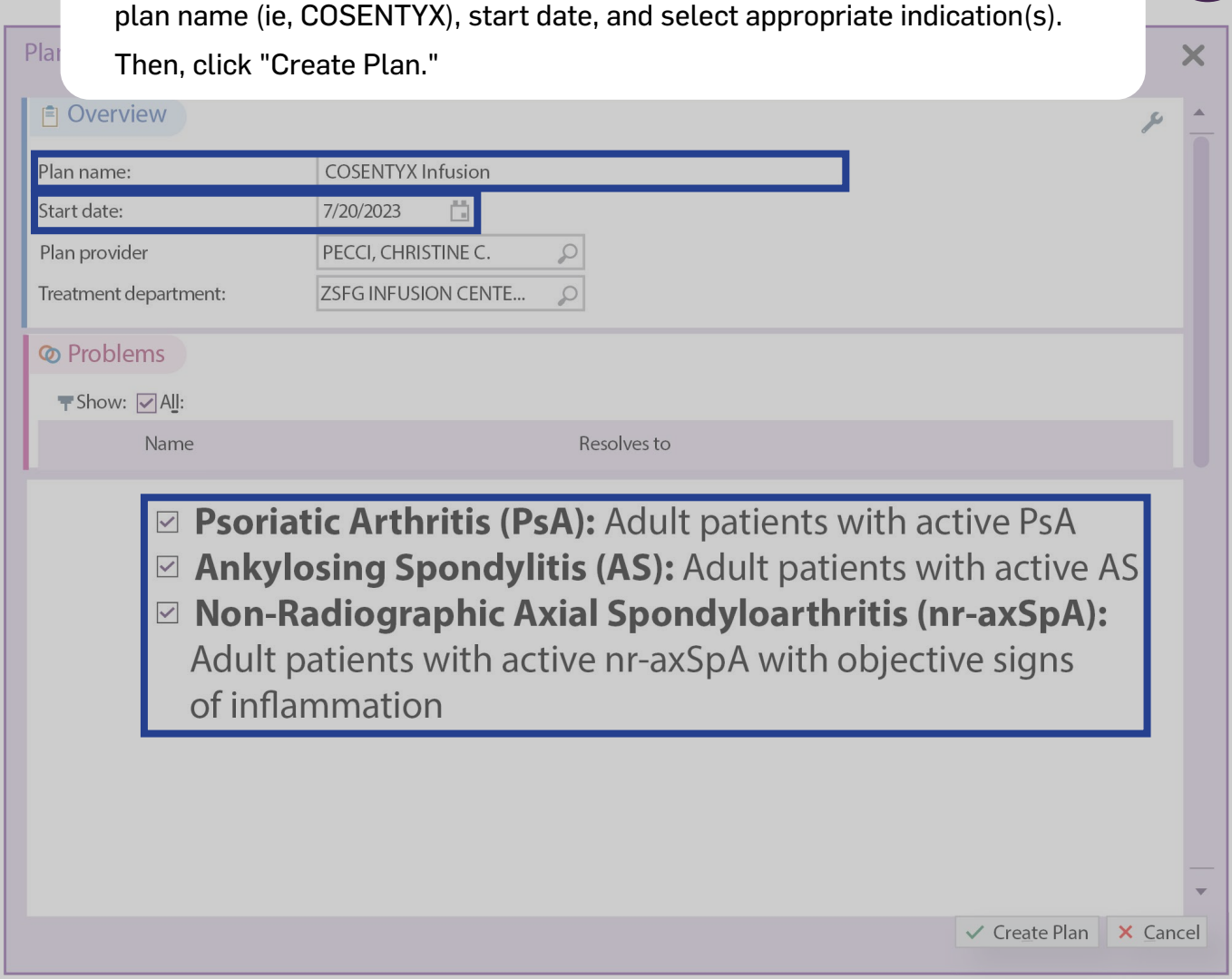
Therapy plans consist of specific sets of orders (eg, medications, labs, imaging, etc) that are administered during scheduled appointments.

A therapy plan includes predefined sets of orders a patient may need (eg, scheduled

IV FORMULATION

To create a new therapy plan, enter all the relevant information, including plan name (ie, COSENTYX), start date, and select appropriate indication(s).

Then, click "Create Plan."



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Ordering the IV Formulation of COSENTYX® Using Therapy Plans

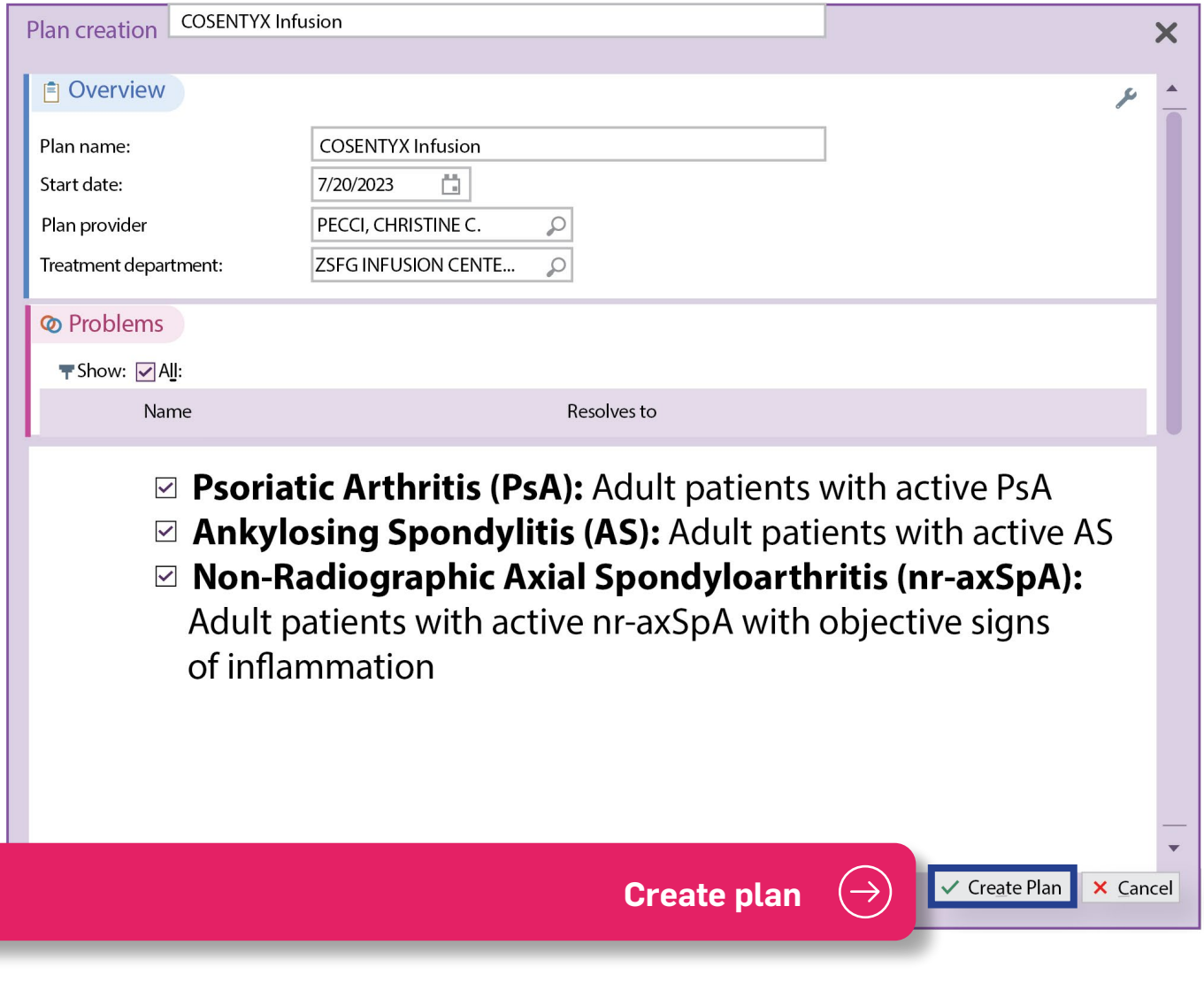
Cosentyx® (secukinumab)

Therapy plans consist of specific sets of orders (eg, medications, labs, imaging, etc) that are administered during scheduled appointments.

A therapy plan includes predefined sets of orders a patient may need (eg, scheduled

IV FORMULATION

Create a new plan Example



Create plan

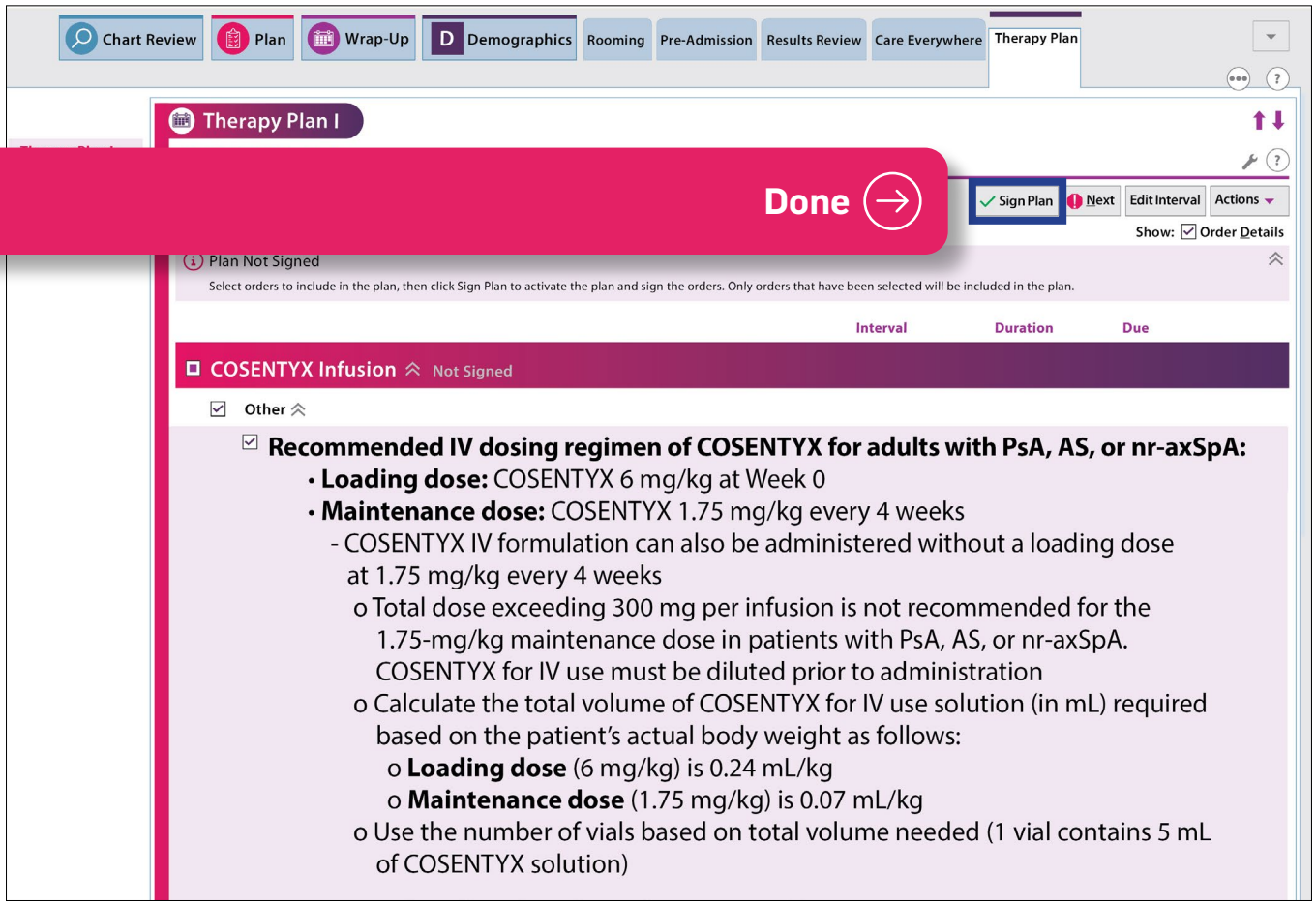
If the therapy plan window within your EHR system look different from what is shown on the next few pages, reach out to your internal IT help desk.

Ordering the IV Formulation of COSENTYX® Using Therapy Plans

Cosentyx® (secukinumab)

Complete all required order questions (denoted by red stop sign), including recommended **medication dosage, dilution and administration instructions**, nursing orders, labs, and special instructions.

Once you have completed all the necessary steps, **sign and complete the order**. Please note that you may need to include an end date for the therapy plan.



For more information on dosing for the IV formulation of COSENTYX, visit Cosentyx-DosingCalculator.com.

Cosentyx® (secukinumab)

IMPORTANT SAFETY INFORMATION

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CONTRAINDICATIONS

COSENTYX® is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients in COSENTYX. Cases of anaphylaxis and angioedema have been reported during treatment with COSENTYX.

WARNINGS AND PRECAUTIONS

Infections

COSENTYX may increase the risk of infections. In clinical trials, a higher rate of infections was observed in COSENTYX treated subjects compared to placebo-treated subjects. In placebo-controlled clinical trials in subjects with moderate to severe PsO, higher rates of common infections, such as nasopharyngitis (11.4% versus 8.6%), upper respiratory tract infection (2.5% versus 0.7%) and mucocutaneous infections with candida (1.2% versus 0.3%) were observed in subjects treated with COSENTYX compared to placebo-treated subjects. A similar increase in risk of infection in subjects treated with COSENTYX was seen in placebo-controlled trials in subjects with PsA, AS and nr-axSpA. The incidence of some types of infections, including fungal infections, appeared to be dose-dependent in clinical trials.

In the postmarketing setting, serious bacterial, viral, and fungal opportunistic infections, and some fatal infections have been reported in patients receiving IL-17 inhibitors including COSENTYX. Cases of Hepatitis B virus reactivation have been reported.

Exercise caution when considering the use of COSENTYX in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, monitor the patient closely and discontinue COSENTYX until the infection resolves.

If signs of Hepatitis B virus reactivation occur, consult a hepatitis specialist. COSENTYX is not recommended for use in patients with active viral hepatitis.

Pre-treatment Evaluation for Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with COSENTYX. Avoid administration of COSENTYX to patients with active TB infection. Initiate treatment of latent TB prior to administering COSENTYX. Consider anti-TB therapy prior to initiation of COSENTYX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients closely for signs and symptoms of active TB during and after treatment.

Inflammatory Bowel Disease

Inflammatory Bowel Disease (IBD) exacerbations, in some cases serious and/or leading to discontinuation of COSENTYX, occurred in COSENTYX treated subjects during clinical trials in PsO, PsA, AS, nr-axSpA, and HS. In adult subjects with HS, the incidence of IBD was higher in subjects who received COSENTYX 300 mg every 2 weeks (Ulcerative Colitis [UC] 1 case, EAIR 0.2/100 subject-years; Crohn's Disease [CD] 1 case, EAIR 0.2/100 subject-years) compared to subjects who received COSENTYX 300 mg every 4 weeks (IBD 1 case, EAIR 0.2/100 subject-years).

Please additional Important Safety Information on page 6.
Please see full Prescribing Information, including Medication Guide.

Cosentyx® (secukinumab)

IMPORTANT SAFETY INFORMATION (cont)

NEXT

WARNINGS AND PRECAUTIONS (cont)

Inflammatory Bowel Disease (cont)

In addition, new onset IBD cases occurred in subjects treated with COSENTYX in clinical trials. In an exploratory trial in 59 subjects with active Crohn's disease [COSENTYX® is not approved for the treatment of Crohn's disease], there were trends toward greater disease activity and increased adverse reactions in subjects treated with COSENTYX as compared to placebo-treated subjects.

Exercise caution when prescribing COSENTYX to patients with IBD. Patients treated with COSENTYX should be monitored for signs and symptoms of IBD.

Eczematous Eruptions

In postmarketing reports, cases of severe eczematous eruptions, including atopic dermatitis-like eruptions, dyshidrotic eczema, and erythroderma, were reported in patients receiving COSENTYX; some cases resulted in hospitalization. The onset of eczematous eruptions was variable, ranging from days to months after the first dose of COSENTYX.

Treatment may need to be discontinued to resolve the eczematous eruption. Some patients were successfully treated for eczematous eruptions while continuing COSENTYX.

Hypersensitivity Reactions

Serious hypersensitivity reactions including anaphylaxis, angioedema, and urticaria have been reported in COSENTYX treated subjects in clinical trials and in the post-marketing setting. If an anaphylactic or other serious allergic reaction occurs, immediately discontinue administration of COSENTYX and initiate appropriate therapy.

The removable caps of the COSENTYX Sensoready® pen and the COSENTYX 1 mL and 0.5 mL prefilled syringes contain natural rubber latex, which may cause an allergic reaction in latex-sensitive individuals. The safe use of the COSENTYX Sensoready pen or prefilled syringe in latex-sensitive individuals has not been studied.

Immunizations

Prior to initiating therapy with COSENTYX, consider completion of all age-appropriate immunizations according to current immunization guidelines. COSENTYX may alter a patient's immune response to live vaccines. Avoid use of live vaccines in patients treated with COSENTYX.

MOST COMMON ADVERSE REACTIONS

Most common adverse reactions (>1%) are nasopharyngitis, diarrhea, and upper respiratory tract infection.

Please additional Important Safety Information on page 5.
Please see full Prescribing Information, including Medication Guide.

Cosentyx® (secukinumab)

NOTES

- Novartis is not responsible for the implementation, testing, and ongoing operation of any EHR tools. If you have any questions pertaining to the use of these guides, please refer to your internal IT/IS department
- The customers (ie, physician, medical group, and integrated delivery network [IDN]) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each customer's EHR system
- Capabilities, functionality, and setup (customization) for each individual EHR system vary. Novartis shall not be responsible for revising the implementation instructions it provides to any customer in the event that 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 Novartis
- While Novartis tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems, and Novartis shall have no liability therefore
- These tools are not designed for and have not been demonstrated to meet any accreditation requirements
- Reference to products is not intended to imply affiliation with or sponsorship of Novartis and/or its affiliates

For more information on how the Novartis Health Information Technology (HIT) Team can collaborate with your organization to identify shared priorities, please email HIT.Novartis@novartis.com

Please see Important Safety Information on pages 5 and 6.
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