ORSERDU®
elacestrant

Access, Distribution, and Reimbursement Guide

INDICATION

ORSERDU (elacestrant) is indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Dyslipidemia:** Hypercholesterolemia and hypertriglyceridemia occurred in patients taking ORSERDU at an incidence of 30% and 27%, respectively. The incidence of Grade 3 and 4 hypercholesterolemia and hypertriglyceridemia were 0.9% and 2.2%, respectively. Monitor lipid profile prior to starting and periodically while taking ORSERDU.

Please see additional Important Safety Information on pages 16 and 17 and full Prescribing Information.

Contents

ORSERDU Product Information

Indication[1]

ORSERDU is indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated (*ESR1*m) advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

Dosing and Administration[1]

Select patients for treatment of ER-positive, HER2-negative advanced or metastatic breast cancer with ORSERDU based on the presence of *ESR1* mutation(s) in plasma specimen using an FDA-approved test.

Convenient daily oral dosing with ORSERDU

- One 345 mg tablet, once daily
- Treat patients until disease progression or unacceptable toxicity occurs

- Take with food
- Tablets should be swallowed whole. Do not chew, crush, or split prior to swallowing

- Should be taken at approximately the same time, each day
- If a dose is missed for more than 6 hours, patient should continue regular dosing the next day*

*If a dose is missed for more than 6 hours or vomiting occurs, skip the dose and take the next dose the following day at its regularly scheduled time.

Dosage Modifications[1]

- Some situations may require dose interruption, adjustment, and/or discontinuation. For information on dose modifications, please see the full **Prescribing Information**

Storage[1]

- Store at 68°F to 77°F (20°C to 25°C)
- Excursions permitted from 59°F to 86°F (15°C to 30°C)

FDA=US Food and Drug Administration.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- **Embryo-Fetal Toxicity:** Based on findings in animals and its mechanism of action, ORSERDU can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ORSERDU and for 1 week after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ORSERDU and for 1 week after the last dose.

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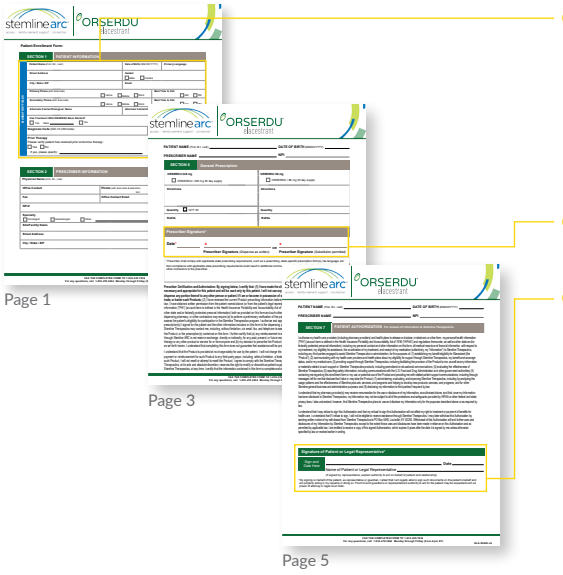
Stemline ARC® Offers Healthcare Professionals, Office Staff, and Patients Comprehensive Support

Getting assistance from Stemline ARC for your ORSERDU patients is simple. **Download and complete the form below to get your patients started.**

Enrollment form >

Submit by fax:
1-833-329-7836

Submit by mail:
Stemline ARC
PO Box 5490
Louisville, KY 40255



- **Remember to fill in the "MANDATORY FIELDS" section** by adding the diagnosis codes (ICD-10-CM code) and select whether the patient received prior endocrine therapy, is *ESR1*m positive, and ER+/HER2-
- **Prescriber signature is required** to enroll patients in the ORSERDU access programs
- **Patient/caregiver signatures are required** to provide consent to enroll in the programs

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Questions?
Connect with a Stemline ARC Patient Advocate
1-833-4-STEMLINE (1-833-478-3654)
9:00 AM to 6:00 PM ET | Monday through Friday

ER+=estrogen receptor positive, ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

Please see Important Safety Information on pages 16 and 17 and full Prescribing Information.

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Once Enrolled, Stemline ARC® Can Help With Access, Reimbursement, and Financial Assistance

Access & Reimbursement Support

Services that may assist you and your office staff, including:

- Benefits investigation and verification
- PA and medical necessity requirements (see **checklist** on the next page)
- Case management

Financial Assistance Programs & Ordering

Information on:

- Financial assistance options for eligible patients*
- Ordering information

Resources

Available comprehensive access and reimbursement-related resources to help grant your patients access to treatment, including:

- ORSERDU Sample Letter of Medical Necessity
- ORSERDU Sample Letter of Appeal

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*In order to be eligible for the ORSERDU Co-pay Card Program, the patient must not have government-funded health insurance (eg, Medicare, Medicaid, TRICARE, or any other federal or state program), must be taking ORSERDU for an FDA-approved indication, and must confirm that they meet all of the eligibility criteria and agree to the rules set forth in the terms and conditions for the program. Patients and healthcare providers are responsible for completing and submitting enrollment forms and coverage or reimbursement documentation. Stemline Therapeutics, Inc. makes no representation or guarantee concerning coverage or reimbursement of any service or item.

Please see Important Safety Information on pages 16 and 17 and full Prescribing Information.

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Navigating PAs and Payer Denial Checklist

Stemline ARC® May Help Educate You on the PA Process

Payers may require a PA that describes your patient's medical history and the reasons why ORSERDU has been prescribed. Various health plans have different requirements. It is important to check with your patient's health plan to ensure you are using the correct form and supplying all the required information. To avoid delays, it is important to include a Letter of Medical Necessity to support the PA submission.

PA Checklist

Helpful reminders for the PA process

- Confirm PA requirements and how the PA should be submitted (eg, fax or phone)
- Determine if the health plan has a specific form that must be used and if it is available online
- Check the health plan's policy for treating ER+/HER2, *ESR1*m advanced or metastatic breast cancer[1] with ORSERDU to ensure medical documentation addresses specific policy requirements
- Use the appropriate billing codes starting on **page 11**

All PA forms must be completed and submitted by a patient's healthcare provider based on their clinical judgment and assessment of the patient's case

Letter of Medical Necessity (*some payers may require this*)

- Be specific in your request (ie, requesting approval of the PA to support the prescribed medication)
- Highlight the clinical assessments that demonstrate the patient need and that the patient meets the health plan medical policy criteria for treatment with ORSERDU
- Include a copy of the health plan medical policy, if available
- Include the physician's contact information

ORSERDU Sample Letter of Medical Necessity

Follow-up Reminders

- Call to make sure the PA request was received
- Keep a record of your phone calls: who you talked to, when, and what was agreed to or discussed
- Document the PA approval number and duration (with written confirmation, if possible)
- Include the PA reference number on the claim form, if possible

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Navigating PAs and Payer Denial Checklist (cont'd)

What Happens Next?

1. **If the PA is approved, be sure to document the PA approval number/date** in the patient's record and make note of the expiration date.

2. **If the PA is denied, you can file an appeal**. Stemline ARC® can support you and provide information about how your office can properly file this paperwork. See the checklist below for additional steps.

PA Denial/Appeal Checklist

Helpful reminders for the PA process

- Review the denial letter to understand the reason for the denial and note any deadlines for next steps
- Compile supporting medical information, documentation, and clinical assessments
- Submit the first appeal per the health plan's process and requirements
- If rejected, submit a second appeal that responds to the health plan's concerns, questions, or requirements
- The appeal policies of many health plans allow up to 2 levels of internal appeal for PA denials
- You may have the right to request an external appeal, which can include a review by an independent expert not affiliated with the health plan or an external review board. Be sure to note any deadlines for these additional appeals

ORSERDU Sample Letter of Appeal

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Stemline ARC® Is Committed to Patients With Their ORSERDU Treatment Journey

There are 2 points of contact for your patient:

1 Stemline ARC Nurse Navigator*

- Provides support and access information for ORSERDU
- Helps set expectations when taking ORSERDU (ie, storage and handling, administration)
- Available to answer some frequently asked patient questions†

2 Stemline ARC Patient Advocate*

- Provides an overview of support services
- Confirms ORSERDU coverage and financial assistance
- Shares helpful resources
- Assists in overall case management

Stemline ARC Nurse Navigators may contact your patient to check in on the progress of their treatment journey

Welcome call

- Introduction to Stemline ARC (ie, starter kit overview, if applicable)
- Confirmation of patient information
- Overview of patient-specific benefits
- What to expect with ORSERDU treatment

Follow-up calls

- May reach out to your patients to provide support as they begin treatment
- Answers any questions the patient may have†
- Helps set expectations when taking ORSERDU (ie, storage and handling, administration)

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Questions?
Connect with a Stemline ARC Patient Advocate
1-833-4-STEMLINE (1-833-478-3654)
9:00 AM to 6:00 PM ET | Monday through Friday

*Stemline ARC Nurse Navigators and Patient Advocates are available to provide resource information and answer questions about financial assistance, insurance benefits, and coverage for ORSERDU.
†This supplemental support is not intended to replace discussions between patients and their healthcare providers.

Please see Important Safety Information on pages 16 and 17 and full Prescribing Information.

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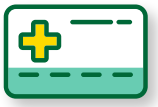
ORSERDU Access Programs Offer Support for Eligible Patients

Once your patients have been enrolled in **Stemline ARC®** and the benefits verification process has been completed, your Stemline ARC Patient Advocate will let your patient know what **financial support alternatives are available to them based on their eligibility**.



ORSERDU Co-pay Card*

Eligible, commercial patients could **pay as little as $0** for their medication

Two ways for patients to get the ORSERDU Co-pay Card

Scan the QR code

OR

Visit

ORSERDUcopay.com

Once on the site, patients can get the card by answering a few questions and providing some basic information.

For more information on the ORSERDU Co-pay Card visit ORSERDUcopay.com

ORSERDU Patient Assistance Program†

Eligible, uninsured, or functionally uninsured patients may be able to access their medication **at no cost**

*Limitations apply. This offer is only available to eligible patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state healthcare program. Stemline Therapeutics, Inc. reserves the right to rescind, revoke, or amend this program without notice. For full eligibility criteria, and terms and conditions, visit ORSERDUcopay.com or call 1-800-519-2140.

†To be eligible for this program, insured patients must have exhausted all other forms of patient assistance and meet financial criteria. Insured and uninsured patients must also meet certain eligibility criteria.

Please see Important Safety Information on pages 16 and 17 and full Prescribing Information.

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A Guide to Process a Prescription for ORSERDU

E-prescribe

Biologics by McKesson or NPI# 1487640314
Oncomed Dba Onco360 or NPI# 1679618151

Consider contacting your EMR representative if Biologics and/or Onco360 are not currently included in your system.

Call the Rx into a specialty pharmacy

Biologics Phone: 1-800-850-4306
Onco360 Phone: 1-877-662-6633

Fax the Rx to a specialty pharmacy

Biologics Fax: 1-800-823-4506
Onco360 Fax: 1-877-662-6355

Be sure the Rx includes:
- Start date
- Dosing instructions (include total dosage, quantity, refills)

Patient information:
- Date of birth
- Phone number
- Diagnosis (ICD-10-CM code and stage of disease)

Additional tips:
- Include front and back of patient's insurance card, including pharmacy benefit
- Add clinical information that supports the treatment decision (including pathology, lab reports, treatment history, description of the treatment plan)

Complete and fax the specialty pharmacy referral form

Biologics Order Form
Scan the QR code or

Click here >

Onco360 Order Form
Scan the QR code or

Click here >

Complete and fax the ORSERDU Enrollment Form

Stemline ARC® Fax: 1-833-329-7836

Scan the QR code or

Click here to register >

A reminder that Biologics and Onco360 may call the prescriber's office to support your efforts with payer approval. Staff should also remind their patients to expect calls from Biologics and Onco360 to arrange delivery and support their care.

EMR=electronic medical record.

Please see Important Safety Information on pages 16 and 17 and full Prescribing Information.

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ORSERDU Billing and Coding

The tables below provide examples of codes that may be required for reimbursement for ORSERDU. Please note, the use of the following codes does not guarantee payment for coverage for any product or service. Please contact the payer or **Stemline ARC® at 1-833-4-STEMLINE (1-833-478-3654), Monday through Friday, 9:00 AM to 6:00 PM ET** for additional coding information.

National Drug Code (NDC) 11-digit[1]

Administration method	Dosage*	NDC 11-digit	Description
Oral	345 mg	72187-0102-03	Bottle of 30 tablets light blue; oval
Oral	86 mg	72187-0101-03	Bottle of 30 tablets light blue; round

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes[2]

ICD-10-CM codes	Description
	Malignant neoplasm of breast
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.11	Malignant neoplasm of central portion of breast, female
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast

*In the EMERALD trial, the 400-mg dose of elacestrant hydrochloride that was used contained approximately 345 mg of elacestrant free base.[1]

Please see Important Safety Information on pages 16 and 17 and full Prescribing Information.

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ORSERDU Billing and Coding (cont'd)

ICD-10-CM diagnosis codes (cont'd)[2]

ICD-10-CM codes	Description
	Malignant neoplasm of breast (cont'd)
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.21	Malignant neoplasm of upper-inner quadrant of breast, female
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.31	Malignant neoplasm of lower-inner quadrant of breast, female
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.41	Malignant neoplasm of upper-outer quadrant of breast, female
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast

Please see Important Safety Information on pages 16 and 17 and full Prescribing Information.

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ORSERDU Billing and Coding (cont'd)

ICD-10-CM diagnosis codes (cont'd)[2]

ICD-10-CM codes	Description
	Malignant neoplasm of breast (cont'd)
C50.51	Malignant neoplasm of lower-outer quadrant of breast, female
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.61	Malignant neoplasm of axillary tail of breast, female
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.62	Malignant neoplasm of axillary tail of breast, male
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.81	Malignant neoplasm of overlapping sites of breast, female
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.91	Malignant neoplasm of breast of unspecified site, female

ORSERDU Billing and Coding (cont'd)

ICD-10-CM diagnosis codes (cont'd)[2]

ICD-10-CM codes	Description
	Malignant neoplasm of breast (cont'd)
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
Z85.3	Personal history of malignant neoplasm of breast
	Metastasis to bone and bone marrow
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
	Metastasis to lung and pleura
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.1	Secondary malignant neoplasm of mediastinum
C78.2	Secondary malignant neoplasm of pleura
C78.30	Secondary malignant neoplasm of unspecified respiratory organ
C78.39	Secondary malignant neoplasm of other respiratory organs

ORSERDU Billing and Coding (cont'd)

ICD-10-CM diagnosis codes (cont'd)[2]

ICD-10-CM codes	Description
	Metastasis to lymph nodes
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
C77.3	Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified
	Metastasis to liver
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
	Metastasis to brain
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges

Important Safety Information for ORSERDU

INDICATION

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- **Embryo-Fetal Toxicity:** Based on findings in animals and its mechanism of action, ORSERDU can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ORSERDU and for 1 week after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ORSERDU and for 1 week after the last dose.

Adverse Reactions

- **Serious adverse reactions** occurred in 12% of patients who received ORSERDU. Serious adverse reactions in >1% of patients who received ORSERDU were musculoskeletal pain (1.7%) and nausea (1.3%). Fatal adverse reactions occurred in 1.7% of patients who received ORSERDU, including cardiac arrest, septic shock, diverticulitis, and unknown cause (one patient each).
- **The most common adverse reactions** (≥10%), including laboratory abnormalities, of ORSERDU were musculoskeletal pain (41%), nausea (35%), increased cholesterol (30%), increased AST (29%), increased triglycerides (27%), fatigue (26%), decreased hemoglobin (26%), vomiting (19%), increased ALT (17%), decreased sodium (16%), increased creatinine (16%), decreased appetite (15%), diarrhea (13%), headache (12%), constipation (12%), abdominal pain (11%), hot flush (11%), and dyspepsia (10%).

Drug Interactions

- **Concomitant use with CYP3A4 inducers and/or inhibitors:** Avoid concomitant use of strong or moderate CYP3A4 inhibitors with ORSERDU. Avoid concomitant use of strong or moderate CYP3A4 inducers with ORSERDU.

Please see additional Important Safety Information on page 17 and full Prescribing Information.

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Important Safety Information for ORSERDU (cont'd)

Use in Specific Populations

- **Lactation:** Advise lactating women to not breastfeed during treatment with ORSERDU and for 1 week after the last dose.
- **Hepatic Impairment:** Avoid use of ORSERDU in patients with severe hepatic impairment (Child-Pugh C). Reduce the dose of ORSERDU in patients with moderate hepatic impairment (Child-Pugh B).

The safety and effectiveness of ORSERDU in pediatric patients have not been established.

ORSERDU is available as 345 mg tablets and 86 mg tablets.

To report SUSPECTED ADVERSE REACTIONS, contact Stemline Therapeutics, Inc. at 1-877-332-7961 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information, including Patient Information.

The information contained in the guide is intended to provide a general understanding of the coding and billing process and is not intended to assist healthcare professionals in obtaining reimbursement for any specific claim. The guide is for informational purposes only and does not represent legal or billing advice. The content here is based on information as of [December 20, 2023], and is subject to change.

References: 1. ORSERDU [prescribing information]. New York, NY: Menarini Stemline, Inc.; 2023. **2.** Centers for Medicare & Medicaid Services. 2024 ICD-10-CM. Accessed December 20, 2023. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm

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