ICOTYDE™
(icotrokinra) tablets

Getting your patients started on ICOTYDE

Biologic coordinator and office staff guide to help patients start treatment

INDICATION

ICOTYDE™ (icotrokinra) 200 mg is indicated for the treatment of moderate to severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infections

Avoid treatment with ICOTYDE in patients with any clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing ICOTYDE. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If a patient develops such an infection and/or is not responding to standard therapy, monitor the patient closely and discontinue ICOTYDE until the infection resolves.

Tuberculosis (TB)

Consider evaluating for TB prior to initiating treatment with ICOTYDE based on clinical judgement. Consider anti-TB therapy prior to initiating ICOTYDE in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after ICOTYDE treatment. Avoid administering ICOTYDE to patients with active TB.

Immunizations

Avoid use of live vaccines in patients during treatment with ICOTYDE. Medications that interact with the immune system may increase the risk of the infection following administration of live vaccines. Prior to initiating therapy with ICOTYDE, complete immunizations according to current immunization guidelines.

Please see full Prescribing Information and Medication Guide for ICOTYDE.

What's inside

This resource includes information to help your patients start and stay on ICOTYDE. Here's what's inside:

- **ICOTYDE OVERVIEW**
- **GETTING STARTED:** ICOTYDE withMe Trial Offer
- **HELPING PATIENTS STAY ON TREATMENT**
- **ICOTYDE withMe PATIENT SUPPORT PROGRAM**
- **PRIOR AUTHORIZATION CONSIDERATIONS**
- **RESOURCES**

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

Most common adverse reactions (≥1%) are headache, nausea, cough, fungal infection, and fatigue. The adverse reactions observed in pediatric patients were consistent with the most common adverse reactions (≥1%) observed in the overall population.

USE IN SPECIFIC POPULATIONS

Moderate or Severe Renal Impairment

Monitor for potential adverse reactions when ICOTYDE is used in patients with an estimated glomerular filtration rate (eGFR) <60 mL/min.

Please see full Prescribing Information and Medication Guide for ICOTYDE.

ICOTYDE™ (icotrokinra) tablets

The **first and only** IL-23R–targeted oral peptide in a once-daily pill[1,2]

Indication[1]

ICOTYDE™ (icotrokinra) 200 mg is indicated for the treatment of moderate to severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg who are candidates for systemic therapy or phototherapy.

Dosing and administration[1]

Wake + Take

Upon waking, take with water on an empty stomach at least 30 minutes before eating

No loading dose or titration required

No messy, time-consuming application

No refrigeration or preparation

Pill not actual size.

NDC[1]

- 57894-201-30

Once a decision has been made to prescribe ICOTYDE, Johnson & Johnson is committed to helping your patients access treatment

IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS (cont'd)

Pregnancy

The available data on the use of ICOTYDE during pregnancy are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.

Please read the full Prescribing Information and Medication Guide for ICOTYDE.

Provide the Medication Guide to your patients and encourage discussion.

cp-564098v1

IL-23R, interleukin-23 receptor; NDC, National Drug Code.

References: 1. ICOTYDE [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Fourie AM, Cheng X, Chang L, et al. JNJ-77242113, a highly potent, selective peptide targeting the IL-23 receptor, provides robust IL-23 pathway inhibition upon oral dosing in rats and humans. *Sci Rep*. 2024;14(1):17515. doi:10.1038/s41598-024-67371-5

ICOTYDE™ (icotrokinra) tablets

ONCE A DECISION HAS BEEN MADE TO PRESCRIBE ICOTYDE

The ICOTYDE Promise: Get patients* started on their ICOTYDE trial in as fast as 1 day†

1 SEND

Send patient's prescription to ICOTYDE withMe

EHR/eRx

Use your EHR to send an eRx. Select **Access Therapy Center – J&J Company**

OR

Patient Enrollment Form (PEF)

Fax/eFax a completed PEF to **ICOTYDE withMe** at **877-711-0349**

To download the PEF scan or click here

For dermatology practices, you may also have access to an EMA® PEF that will pull key information into the form automatically

2 START

Patient eligibility will be confirmed by ICOTYDE withMe*

Eligible patients must be:

- Commercially insured
- ≥12 years of age
- Being treated for moderate to severe plaque psoriasis

Once confirmed, the patient can receive a 30-day supply of ICOTYDE at no cost to see if it's right for them

- If the patient opts in, ICOTYDE will be sent **directly to your patient** from **J&J Access Therapy Center**

Patients must answer a call from "Healthcare" (888-796-8154) to opt in and confirm their shipment

Please remind your patient to save this number in their phone and answer the call†

The patient support and resources provided by ICOTYDE withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe ICOTYDE.

*Patients must be commercially insured, ≥12 years of age, and being treated for moderate to severe plaque psoriasis. See program requirements at ICOTYDEwithMeTrial.com.

†Patient MUST answer the phone call from ICOTYDE withMe and opt in or product will NOT be shipped.

EHR, electronic health record; EMA®, Electronic Medical Assistant®; eRx, electronic prescription.

Please see full Prescribing Information and Medication Guide for ICOTYDE.

ICOTYDE™ (icotrokinra) tablets

Help your eligible patients stay on treatment—with or without coverage

3 STAY

To continue patients on therapy:

If ICOTYDE is covered*

- Your **practice will be alerted** to submit a PA
- Once the PA is approved, the prescription will be triaged to a specialty pharmacy and **shipped directly to your patient**
- Eligible patients may pay **as little as $0 per month** for ICOTYDE through the **ICOTYDE withMe Savings Program**†

†Maximum program benefit per calendar year shall apply. Terms expire at the end of each calendar year. Offer subject to change or end without notice. Restrictions, including monthly maximums, may apply. See program requirements at ICOTYDEwithMeSavings.com.

If ICOTYDE is not covered

- If ICOTYDE is not covered,‡ or if coverage is delayed >5 business days or denied, your patient may be eligible for the **ICOTYDE withMe Access Program**§
- You must **submit an appeal** within 90 days after your patient receives their shipment of ICOTYDE from the ICOTYDE withMe Access Program for your patient to remain eligible
- Eligible patients can receive ICOTYDE **at no cost for up to 3 years** or until the patient's commercial insurance covers ICOTYDE

Since ICOTYDE is a new treatment, your patients may not have coverage as we wait for health plans to update coverage policies

ICOTYDE withMe helps patients who are underinsured or have no healthcare coverage find cost support options that can make treatment more affordable. Call your Case Manager team at **844-4withMe (844-494-8463)** or visit JNJwithMe.com/hcp/ICOTYDE for more information on affordability programs that may be available.

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*Individual patient coverage may vary.
‡Applicable only for the 12-month period post-FDA approval of ICOTYDE for moderate to severe plaque psoriasis.
§Patients must be aged ≥12 years with an on-label ICOTYDE prescription and commercial insurance. See program requirements at ICOTYDEwithMeAccess.com.

FDA, U.S. Food and Drug Administration; PA, prior authorization.

Please see full Prescribing Information and Medication Guide for ICOTYDE.

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ICOTYDE withMe

ICOTYDE withMe provides support to help your patients start and stay on treatment

Enroll your patients in ICOTYDE withMe for free access to personalized support and resources throughout their treatment

Office Educational Support

The ICOTYDE withMe team works together to provide customized patient fulfillment support. Your dedicated support team includes:

ICOTYDE withMe Case Manager

Highly trained across all ICOTYDE withMe offerings and skilled at matching patients to the right support

Johnson & Johnson Field Reimbursement Manager (FRM)

Works directly with your Case Manager team to support your patients on ICOTYDE

Your Case Manager and FRM can pull in more experts as needed, including a Reimbursement Specialist, Care Liaison, and/or Specialty Pharmacy Liaison.

The patient support and resources provided by ICOTYDE withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe ICOTYDE.

Please see full Prescribing Information and Medication Guide for ICOTYDE.

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ICOTYDE withMe

ICOTYDE withMe provides support to help your patients start and stay on treatment

Additional support for your patients

Access & Affordability Support

ICOTYDE withMe helps your patients learn about access and cost support options to assist them throughout their treatment.

Dedicated Nurse Guide

A registered nurse who is committed to helping your patients navigate treatment by providing appointment reminders and supplemental education about their treatment and condition. Nurse Guides do not provide medical advice.

Specialty Pharmacy Enhanced Services

Our contracted specialty pharmacies handle prescription transfers and sponsored communications about starting and staying on treatment. Enhanced services provided by each specialty pharmacy may vary.

Once enrolled, your patients will also receive a Patient Welcome Kit that includes a welcome note, patient educational materials, and more

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Reminders and tips for completing PAs for your patients

Once ICOTYDE has commercial coverage, each health plan may have its own unique PA form with varying requirements. It is important to gather necessary information during the patient's first appointment to ensure an effective process with minimal delays.

3 essentials for effectively completing a PA form:

1. **Diagnosis must match FDA indication for ICOTYDE**
   - Diagnosis must be moderate to severe plaque psoriasis in adults and pediatric patients 12 years of age and older who weigh at least 40 kg
   - Patients must be candidates for systemic therapy or phototherapy even if not on treatment
2. **Tuberculosis (TB) test results must be included if required by the health plan**
3. **Notes of previously used medicines, response to therapy** (patient has tried and failed topicals, phototherapy, and/or DMARDs), **and other medical record documentation must be included**, if required by the health plan

Be sure to have the following information on hand to help you complete the PA form:

Patient information

- **Patient insurance information**
  - Copy of the patient's prescription card (front and back)
  - Copy of the patient's health insurance card (front and back)
- **Patient contact information (phone and email preferred)**

Diagnosis/clinical information

- **ICD-10-CM code**
  - **L40.0 (Psoriasis vulgaris)**
- **Supporting clinical information**
  - Lab results and dates
  - Photographs of affected areas
  - PASI score/IGA score
  - Percent BSA coverage
  - Disease severity
- **Patient medication history** (including treatments from previous healthcare providers)
  - Duration of therapy (including conventional therapy)
  - Clinical response
  - Medication allergy
  - Strength
  - Schedule

BSA, body surface area; DMARD, disease-modifying antirheumatic drug; FDA, U.S. Food and Drug Administration; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; IGA, Investigator's Global Assessment; PA, prior authorization; PASI, Psoriasis Area and Severity Index.

Please see full Prescribing Information and Medication Guide for ICOTYDE.

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Sample ICOTYDE PA form

Here is an example of what a PA form for ICOTYDE may include. Remember, all health plans have different criteria. Some may require more or less detail than what is shown here as an example. Be sure to look up the required form for each patient, depending on their insurance.

Sections 1 and 2

Include information about patient's insurance—such as their **Member ID** and **Group #**—and your practice, such as your prescriber's **NPI #**

Sections 3 and 4

Health plans will **require confirmation of diagnosis via ICD-10-CM code**. They will also ask for varying levels of detail regarding the patient's medical history

Please note, you may specifically see a request for a negative TB test

Section 5

Plans will likely **require documentation that the patient has tried and failed other therapies** before approving ICOTYDE, such as topical therapies, phototherapies, or disease-modifying drugs. The exact parameters—which treatments and duration—will vary by plan. Remember, this may include treatments from prior healthcare providers

Section 6

PA forms will often **require the prescription information, including the physician's signature**. Be sure to work with your practice's prescriber to obtain the necessary signatures

Section 1: Patient information		Section 2: Physician information	
Patient name		Prescribing physician	
Address		Office address	
City, State, Zip		City, State, Zip	
Patient telephone #		Office contact name	
Patient ID		Office telephone #	
Date of birth	Weight	Fax #	NPI #

Section 3: Diagnosis

Diagnosis for drug requested (must include ICD-10-CM code): _____

Section 4: Patient medical information

a. Is the patient's chronic plaque psoriasis classified as moderate to severe? ☐ Yes ☐ No

b. Is there involvement of at least X% of body surface area? ☐ Yes ☐ No

c. Is the Psoriasis Area and Severity Index (PASI) score X or greater? ☐ Yes ☐ No

d. Has the patient received a negative test for tuberculosis (TB) in the past X months? Please attach lab results, including x-ray. ☐ Yes ☐ No

Section 5: Prior therapies

a. Does the patient have a documented history of failure, contraindication, or intolerance to any of the following? ☐ Yes ☐ No

Check all that apply and list the drug(s) on the line provided below:

☐ Topical steroids available by prescription only _____

☐ Topical nonsteroids available by prescription only _____

☐ Methotrexate _____

☐ Phototherapy _____

Section 6: Prescription information

Quantity: _____ Refill: _____ month(s)

Instructions (include dose): _____

every _____ ☐ day(s) ☐ week(s) ☐ month(s)

Physician's signature:

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; ID, identification; NPI, National Provider Identifier; PA, prior authorization; TB, tuberculosis.

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Additional resources to help you support your patients

Click the buttons below to view useful ICOTYDE access and reimbursement materials. These resources and more can also be found at JNJwithme.com/hcp/ICOTYDE

- Sample Letter of Medical Necessity
- Letter of Medical Necessity Brochure
- Patient Enrollment Form
- Sample Letter of Exception
- Annotated Patient Enrollment Form
- Patient Affordability Options
- Sample Letter of Appeal
- Have your patients scan and save the ICOTYDE withMe contact to their phone
- Patient Getting Started One Pager

My Field Reimbursement Manager

Name: _____

Phone: _____

Email: _____

My Case Manager

Name: _____

Phone: _____

Email: _____

For access-related troubleshooting and questions about specific patient cases, contact your Field Reimbursement Manager or your ICOTYDE withMe Case Manager at 844-494-8463 (8:00 AM–8:00 PM ET)

EMA®, Electronic Medical Assistant®.

Please see full Prescribing Information and Medication Guide for ICOTYDE.

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