

Billing & Coding Guide for the Intravenous (IV) Formulation of COSENTYX® (secukinumab)

A useful tool for navigating the reimbursement landscape.

For additional support, reach out to your dedicated Access and Reimbursement Team Member or contact COSENTYX® Connect Patient Support



Phone: 1-844-COSENTYX (1-844-267-3689)



Fax: 1-844-666-1366 or 1-800-343-9117



Online: ReadySetCOSENTYX.com

Please see Important Safety Information on pages 16 and 17.
Please see full Prescribing Information, including Medication Guide.

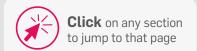


Overview

We know that navigating insurance and reimbursement can be a challenge.

This guide is intended to provide an overview of coding and coverage information related to the IV formulation of COSENTYX® (secukinumab). Healthcare professionals (HCPs) can reference this guide, in addition to other resources, to determine for themselves the appropriate claims to file for the IV formulation of COSENTYX and related services. Novartis does not guarantee payment or coverage for any product or service.

Information specific to coding and billing is subject to change without notice and should be verified by the provider for each patient prior to treatment. It is always the provider's responsibility to determine the appropriate healthcare setting, and to submit true and correct claims for the products and services rendered. Providers should contact third-party health plans for specific information on their coding, coverage and payment policies, and fee schedules.



- This guide is interactive–keep an eye out for callouts to see where you can click
- Clickable purple terms used throughout this guide are defined in glossary

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 ${\it ICD-10-CM}, International\ Classification\ of\ Diseases,\ Tenth\ Revision,\ Clinical\ Modification.$



Basic coverage information

Coding and billing requirements for the IV formulation of COSENTYX® (secukinumab) vary based on many factors, including the site of service where the drug is administered, the type of insurance the patient has, and the benefit under which the IV formulation of COSENTYX is covered.

Site of service

The IV formulation of COSENTYX is intended for use under the guidance and supervision of a physician. For most health plans, the site of service will affect the coding and billing requirements. This guide provides information on coverage, coding, and billing for the IV formulation of COSENTYX when administered in physicians' offices, hospital outpatient settings, and stand-alone infusion centers.

Health plan type1

Coverage, as defined by each health plan type and benefit package, may vary depending on the site of service and the patient's status and medical history.

Medicare Medicaid Private health plans Medicare typically covers and Medicaid coverage and Private health plans may separately reimburses drugs payment can vary by state cover provider-administered provided in the physician's or by the specific managed treatments and the medical office as well as most drugs Medicaid plan. Providers services associated with their provided in the hospital should check with the state administration. However, outpatient department that program or plan for specific there may be restrictions on are not self-administered coverage information for all coverage, such as special and are provided incident to a health plan types for requirements for distribution physician service. fee schedules. and precertification. Private health plans may also vary in Coverage under Medicare the payment methods they Advantage can vary by plan. use to reimburse the sites of Providers should check service where the treatments with the patient's plan for are administered. specific coverage and payment information.



Contact your Access and Reimbursement Team Member to better understand coverage for the IV formulation of COSENTYX.

Most health plans cover physician-administered products under a medical benefit rather than a pharmacy benefit. In the case of Medicare, provider-administered treatments will typically be covered under Part B. However, private health plans and Medicaid may require that physicians order the treatment through a specialty pharmacy. Specialty pharmacies may bill the health plan under the medical or pharmacy benefit, depending on what that plan requires. Additionally, Medicare Advantage health plans may cover the treatment in a similar way to private health plans depending on the benefit design of the patient.

Reference: 1. Tikkanen R, Osborn R, Mossialos E, Djordjevic A, Wharton GA. International health care system profiles: United States. Published June 5, 2020. Accessed June 26, 2023. https://www.commonwealthfund.org/international-health-policy-center/countries/united-states



Drug codes

The table below provides common procedure and drug codes that may be related to administration of the IV formulation of COSENTYX® (secukinumab) in the physician office setting.

National Drug Code (NDC)1

The <u>NDC</u> is a unique, 10- or 11-digit, 3-segment number. It is a universal product identifier for drugs in the United States present on all over-the-counter and prescription medication packages and inserts. Many NDC numbers listed on drug packaging are in 10-digit format.

An 11-digit NDC code may be derived from the 10-digit code. Many health plans require the use of the 11-digit code for proper billing.

Please note: Because many practice management systems automatically remove the hyphens, be sure that they are excluded from submission on the claim. Check with the patient's health insurance provider to determine sequence requirements.

Trade name	Drug strength and dose	10-digit NDC number	11-digit NDC number
COSENTYX	125 mg/5 mL (25 mg/mL) single-dose vial for dilution	0078-1168-61	00078-1168-61



Contact your Access and Reimbursement Team Member to better understand NDC codes for the IV formulation of COSENTYX.



Drug codes (cont)

Healthcare Common Procedure Coding System (HCPCS) Level II code(s)¹

HCPCS Level II codes are used to identify drugs, supplies, medical procedures, and other services. In the absence of a product-specific code, a not-otherwise-classified HCPCS code is required. Health plans may also require the NDC. HCPs should contact third-party health plans for specific information on their coding, coverage, and payment policies.

A miscellaneous code is typically used until a permanent code is implemented. A product-specific code may be available within 6 to 9 months after approval depending on approval timing. The timeline for a product-specific code is determined by the Centers for Medicare & Medicaid Services (CMS).

For Physician Offices

HCPCS code	Descriptor	Setting of care	Billing unit
J3590	Unclassified biologic	Physician's office, hospital outpatient setting, stand-alone infusion center	Bill 1 unit per infusion

For Hospital Outpatient Departments

HCPCS code	Descriptor	Setting of care	Billing unit
C9166*	Injection, secukinumab, intravenous, 1 mg	Only valid for Medicare on claims for hospital outpatient department services and procedures when using the CMS-1450 (UB-04) or equivalent form	Bill 1 unit per 1 mg

^{*}New C-code C9166 is now available for the IV formulation of COSENTYX® (secukinumab), effective for dates of service on or after April 1, 2024, until the effective date of a product-specific HCPCS J-code.

Reference: 1. Centers for Medicare & Medicaid Services. HCPCS quarterly update. Accessed March 13, 2024. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update



Drug codes (cont)



Modifiers

Modifiers play a crucial role in coding and billing processes. They provide additional information about a service or procedure without changing its definition or code. By using modifiers, healthcare providers can indicate specific circumstances such as route of administration, wasted product, and more. To determine the applicability of a modifier, it is recommended to consult the relevant CMS manuals.

Route of administ	ration modifiers ¹
Modifier	Description
JA	Administered intravenously

All Medicare Administrative Contractors (MACs) have issued guidance that the JA modifier is required when billing for the IV formulation of COSENTYX® (secukinumab) to differentiate it from the subcutaneous formulation.

W	asted-product modifiers ²
Modifier	Description
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient

If there were any discarded amounts of COSENTYX, the JW modifier should be used. The JW modifier is designated for the discarded or unused portion of the drug. The JZ modifier is used to report that no amount of drug was discarded and the claim is eligible for payment. The modifier should only be used for claims that bill single-dose container drugs such as COSENTYX.^{2,3}

- ► The standard practice is to record a unit of 1 regardless of how many vials are used when billing with a miscellaneous HCPCS code (eg, J3590)
- Discarded units are billed on another line using the JW modifier and also noted in additional information (Box 19 of the <u>CMS-1500</u> form) or remarks (Box 80 of the <u>CMS1450/UB-04</u> form)
- ▶ Be sure to bill 1 unit on the same line as the JW modifier when billing for wastage when using a miscellaneous J-code

References: 1. Centers for Medicare & Medicaid Services. Billing and coding: complex drug administration coding. Accessed March 14, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58527&ver= 35&= 2. Centers for Medicare & Medicaid Services. Medicare program discarded drugs and biologicals—JW modifier and JZ modifier policy. Accessed June 9, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf 3. COSENTYX. Prescribing information. Novartis Pharmaceuticals Corp.



Current Procedural Terminology (CPT) codes¹

<u>CPT</u> codes are the most widely accepted codes for reporting medical procedures and services under government and private health plans. Please bill for administration according to the appropriate type of services rendered when administering COSENTYX® (secukinumab).

Туре	Code	Description
CPT code*	96XXX	Check the policy for the patient's payer to confirm the appropriate administration code

^{*}CPT © 2023 American Medical Association. All rights reserved.





We are here to help you help your patients.

For additional support and resources, reach out to your Access and Reimbursement Team Member or visit **ReadySetCosentyx.com**.

Reference: 1. American Medical Association (AMA). CPT Professional 2023 and E/M Companion 2023 Bundle. AMA; 2023.



Potential *ICD-10-CM* diagnosis codes

The codes listed are provided for educational purposes only and are not a guarantee of coverage or reimbursement. Coverage and reimbursement may vary significantly by health plan, patient, and setting of care. It is the sole responsibility of the HCP to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient. The codes included on the following pages are included as examples of potential codes that may be relevant for the IV formulation of COSENTYX® (secukinumab).

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes¹

<u>ICD-10-CM</u> diagnosis codes identify why a patient may need treatment (eg, conditions, diseases, related health problems, abnormal findings) and document the medical necessity for a patient to receive treatment with COSENTYX. You should review the health plan's guidance to ensure appropriate codes are selected based on the patient's medical record.

are selected	d based on the patient's r	medical record.
Disease	Possible ICD-10-CM code	Descriptor
PsA	L40.50	Arthropathic psoriasis, unspecified*
	L40.51	Distal interphalangeal psoriatic arthropathy
	L40.52	Psoriatic arthritis mutilans
	L40.53	Psoriatic spondylitis
	L40.59	Other psoriatic arthropathy
Disease	Possible ICD-10-CM code	Descriptor
AS	M45.0	Ankylosing spondylitis of multiple sites in spine
	M45.1	Ankylosing spondylitis of occipito-atlanto-axial region
	M45.2	Ankylosing spondylitis of cervical region
	M45.3	Ankylosing spondylitis of cervicothoracic region
	M45.4	Ankylosing spondylitis of thoracic region
	M45.5	Ankylosing spondylitis of thoracolumbar region
	M45.6	Ankylosing spondylitis of lumbar region
	M45.7	Ankylosing spondylitis of lumbosacral region
	M45.8	Ankylosing spondylitis of sacral and sacrococcygeal region
	M45.9	Ankylosing spondylitis of unspecified sites in spine*
Disease	Possible ICD-10-CM code	Descriptor
nr-axSpA	M45.A0	Non-radiographic axial spondyloarthritis of unspecified sites in spine*
	M45.A1	Non-radiographic axial spondyloarthritis of occipito-atlanto-axial region
	M45.A2	Non-radiographic axial spondyloarthritis of cervical region
	M45.A3	Non-radiographic axial spondyloarthritis of cervicothoracic region
	M45.A4	Non-radiographic axial spondyloarthritis of thoracic region
	M45.A5	Non-radiographic axial spondyloarthritis of thoracolumbar region
	M45.A6	Non-radiographic axial spondyloarthritis of lumbar region
	M45.A7	Non-radiographic axial spondyloarthritis of lumbosacral region
	M45.A8	Non-radiographic axial spondyloarthritis of sacral and sacrococcygeal region
	M45.AB	Non-radiographic axial spondyloarthritis of multiple sites in spine

^{*}When billing with an unspecified ICD-10-CM code, check with payer for applicability.

AS, ankylosing spondylitis; nr-axSpA, non-radiographic axial spondyloarthritis; PsA, psoriatic arthritis.

 $\textbf{Reference: 1.} \ \, \text{Codify by AAPC.} \ \, \textit{ICD-10-CM} \ \, \text{codes lookup.} \ \, \text{Accessed July 27, 2023.} \ \, \text{https://www.aapc.com/codes/icd-10-codes-range/\#:-:text=TheInternationalClassificationofDiseasesexternalcausesofinjuries}$



Setting of care codes

Place of Service (POS) codes¹

POS codes are used to indicate the setting in which a service was provided. The Centers for Medicare & Medicaid Services (CMS) maintains a database of POS codes commonly used in the healthcare industry. Below are examples of some common POS codes. Review the full listing of the POS codes on the CMS website and consult your health plan's guidance to determine the correct code for your institution.

Service	Code	Description
Office	11	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the healthcare professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
On Campus— Outpatient Hospital	22	A portion of a hospital's main campus, that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Description change effective January 1, 2016.)
Independent Clinic*	19	A portion of an off-campus, hospital provider-based department, that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Effective January 1, 2016.)

Hospital revenue codes²

Specific forms, such as the **UB-04 (CMS-1450) form**, require documentation of revenue codes associated with services provided to patients.

Below are commonly used revenue codes for processing claims for products, such as COSENTYX® (secukinumab). This is not an all-inclusive list of revenue codes that could be used, and it is recommended to review individual health plan guidance to determine the appropriate codes for the IV formulation of COSENTYX.

Revenue code	Description
0250	Pharmacy, General
0260	IV (Intravenous) Therapy, General
0510	Clinic, General
0636	Pharmacy, Drugs requiring detailed coding

^{*}An independent diagnostic testing facility shall not be allowed to bill for any CPT or HCPCS codes that are solely therapeutic.

References: 1. Centers for Medicare & Medicaid Services. Place of service code set. Accessed July 25, 2023. https://www.cms.gov/medicare/coding/place-of-service-codes/place_of_service_code_set_June_2023 2. Noridian Healthcare Solutions. Revenue codes. Accessed July 25, 2023. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes



Submitting claims: claim filing checklist

After your patient has been administered the IV formulation of COSENTYX® (secukinumab), a claim for reimbursement is submitted to their health plan. When submitting a claim, it is a best practice to understand the health plan's specific coding and billing requirements and ensure that the submitted claim is as complete as possible. You may want to reference the following general tips when filing claims for the IV formulation of COSENTYX:

Use appropriate codes to report the patient's condition, the drugs the patient received, and the services you provided
► ICD-10-CM code
► CPT code
► HCPCS code
Dosage and strength (if applicable)
► Method of administration
▶ NDC number
Attach additional information to the claim if necessary
▶ Letter of medical necessity
▶ Prescribing Information
▶ Patient notes
Ensure that the appropriate amount of units are billed based on the codes used, especially when using a miscellaneous code
Review claim for accuracy, including patient identification numbers and coding
File claim as soon as possible and within health plan filing time limits
Reconcile claim reports promptly and thoroughly to ensure claims have been appropriately processed and paid
Verify that payment amounts correspond with your public health plan allowables and your private health plan contracts



Submitting claims: common errors

Tips to address common errors when billing with a miscellaneous HCPCS code

Billing and coding for COSENTYX® (secukinumab) is a critical step in the overall process to ensure timely reimbursement from health plans. The following tips can help support more accurate billing. Keep in mind, all box numbers noted below are based on the CMS-1500 form.

- Box 19 (Additional Claim Information): Ensure Box 19 has the required information when using a miscellaneous HCPCS code (eg, J3590). Please Note: Payers may have varying requirements for data to be included
 - ▶ Enter the Drug Name (COSENTYX), Route of Administration (IV Infusion), Dose Administered (mg), Dose Wasted (mg), and 11-digit NDC number. Be sure that the number of mg administered and mg wasted add up to an appropriate number of total vials used. Payers may have varying requirements for data included in Box 19—please check with applicable payer policies to ensure successful submission¹
 - If there are character limits in your EMR/billing software, the most important information to include is Drug Name, Route of Administration, Dose Administered, and Dose Wasted
 - Keep in mind that the NDC can be included in the shaded area of above Box 24A and should inform the adjudicator of the Vial Size
- Required Product Modifiers: Be sure to include the appropriate modifier based on the amount administered
 - ► As of January 2024, all Medicare Administrative Contractors require the use of the **JA modifier** when billing for the IV formulation of COSENTYX¹
 - ▶ The JW modifier should be used when there is wastage, which is the most common scenario due to the weight-based dosing for the IV formulation of COSENTYX²
 - The JW modifier should be billed on a separate line
 - ▶ The JZ modifier should only be used when there is zero wastage²
 - The JZ modifier should be billed on the same line as the JA modifier
- **Billing Units:** The standard practice is to record a unit of 1 regardless of how many vials are used when billing with a miscellaneous HCPCS code (eg, J3590)²
 - ▶ The details in Box 19 and the NDC number will be used by the adjudicator of the claim to determine reimbursement of the number of vials

Reimbursement Disagreements: If you have been reimbursed for a claim and you disagree with your reimbursement amount, there are several ways this can be managed. Be sure to contact the health plan or Medicare Administrative Contractor to understand how they want to proceed. They may require you to

- 1) reopen a claim
- 2) submit an appeal or redetermination
- 3) resubmit with changes

EMR, electronic medical record; HCPCS, Healthcare Common Procedure Coding System; IV, intravenous; NDC, National Drug Code.

References: 1. Centers for Medicare & Medicaid Services. Billing and coding: complex drug administration coding. Accessed March 14, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58527&ver=35&= 2. Centers for Medicare & Medicaid Services. HCPCS quarterly update. Accessed March 13, 2024. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update



Submitting claims: sample forms

Physician's office: sample CMS-1500 form

The IV formulation of COSENTYX® (secukinumab) and the associated services provided in a physician office are billed on the CMS-1500 claim form or its electronic equivalent. A sample CMS-1500 form for billing the IV formulation of COSENTYX is provided below.¹ The sample claim form provided is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party health plans for specific information on their coding, coverage, payment policies, and fee schedules.

	HEALTH INSURANCE CLAIM FORM APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC				
	PICA	50) 02/12		PICA	
		— HEALTH PLAN — BLK LUNG — I	1a. INSURED'S I.D. NUMBER (For Program i	n Item 1	
	2. PATIENT'S NAME (Last Name, First Name, Middle Initial)	(Member ID#) (ID#) (ID#) (ID#) 3. PATIENT'S BIRTH DATE SEX MM DD YY	4. INSURED'S NAME (Last Name, First Name, Middle Initial)		
		MM DD YY			
	5. PATIENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other	7. INSURED'S ADDRESS (No., Street)		
	СПУ	Self Spouse Child Other STATE 8. RESERVED FOR NUCC USE	СПУ	STATE	
	ZIP CODE TELEPHONE (Include Area Cod	o o	ZIP CODE TELEPHONE (Include Area C	\\ \\	
	()	July 1	ZIP CODE TELEPHONE (Include Area C	-ode)	
	9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initia	itial) 10. IS PATIENT'S CONDITION RELATED TO:	11. INSURED'S POLICY GROUP OR FECA NUMBER		
	a. OTHER INSURED'S POLICY OR GROUP NUMBER	a, EMPLOYMENT? (Current or Previous)	a. INSURED'S DATE OF BIRTH SEX		
		YES NO	MM DD YY	F 🔲	
	b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? PLACE (State)	b. OTHER CLAIM ID (Designated by NUCC)		
	c. RESERVED FOR NUCC USE	c. OTHER ACCIDENT?	i c. INSURANCE PLAN NAME OR PROGRAM NAME		
		YES NO			
	d. INSURANCE PLAN NAME OR PROGRAM NAME	10d. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, an	nd 9d.	
	READ BACK OF FORM BEFORE COMI 12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I autho	MPLETING & SIGNING THIS FORM.	INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I as payment of medical benefits to the undersigned physician or a signature.	uthorize	
	to process this claim. I also request payment of government benefit below.	efits either to myself or to the party who accepts assignment	services described below.	supplier	
	SIGNED	DATE	SIGNED		
	14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMI	MP) 15. OTHER DATE MM DD YY	16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCU	PATION YY	
	17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	17a.	FROM TO 1 18. HOSPITALIZATION DATES RELATED TO CURRENT SERV MM DD YY MM DD 1	/ICES	
		17b. NPI	FROM TO		
)	19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) Cosentyx, IV Infusion, XXmg Administer	red, XXmg Wasted, 00078-1168-61	20. OUTSIDE LAB? \$ CHARGES		
	21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-	A-L to service line below (24E) ICD Ind.	22. RESUBMISSION ORIGINAL REF. NO.		
١	A. L40.50 B. L	C D	23. PRIOR AUTHORIZATION NUMBER		
/	F. L. J. L.	G. L. H. L.			
\	From To PLACE OF	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) DIAGNOSIS	DAYS EPSUI ID. REND	J. ERING	
7	MM DD YY MM DD YY SERVICE EMG C N400078116861 ML 1.0	CPT/HCPCS MODIFIER POINTER		DER ID. #	
'		J3590 JA (E)A	(F)1 NPI		
2	MM DD YY MM DD YY	J3590 JA JW A	1		
3	MM; DD; YY MM; DD; YY	96XXX			
		CONST	1 NPI		
4			NPI NPI		
5					
			NPI	_	
6			NPI NPI		
	25. FEDERAL TAX I.D. NUMBER SSN EIN 26. PATI	TIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO	28. TOTAL CHARGE 29. AMOUNT PAID 30. Rsvc	ı tor NU	
	31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS 32. SER	RVICE FACILITY LOCATION INFORMATION	33. BILLING PROVIDER INFO & PH # ()		
	(I certify that the statements on the reverse apply to this bill and are made a part thereof.)		·		
			İ		



Submitting claims: sample forms (cont)



Box 19

Enter the Drug Name (COSENTYX), Route of Administration (IV Infusion), Dose Administered (mg), Dose Wasted (mg), and 11-digit NDC number. Payers may have varying requirements for data included in Box 19—please check with applicable payer policies to ensure successful submission.



Box 21

Indicate diagnosis using appropriate ICD-10-CM code(s) associated with the claim.²



Box 24A

In the non-shaded bottom section, list the date(s) of service. In the shaded section, list the N4 indicator first, then the 11-digit NDC number, followed by the unit of measurement qualifier and the unit quantity (Example N40078116861ML1.0).³ Note that this may not be required for every payer if NDC is already included in Box 19.



Box 24D

Enter the appropriate HCPCS code accompanied by the appropriate modifier as required by the health plan, or if needed based on dose given to patient (JA modifier is required by Medicare when billing for the IV formulation of COSENTYX® [secukinumab]). See additional information on modifiers needed for COSENTYX on page 6.4 For administration enter the appropriate *CPT* code (96XXX).5 Please note, payer policies may vary in regard to specific coding requirements.



Box 24E

Enter the diagnosis code reference letter as shown in Box 21 to relate the date of service and the procedures performed for the primary diagnosis. If there is more than one diagnosis required with a procedure code, only reference one letter from Box 21



Box 24G

Include the appropriate number of billing units. When using a miscellaneous code, bill 1 unit for both drug administered as well as drug wasted regardless of how many vials were used. Details for the adjudicator are found in Box 19 to confirm proper billing.

IMPORTANT INFORMATION: The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for those products and services rendered. Providers should contact third-party health plans for specific information on their coding, coverage, and payment policies. Information and materials are provided to assist healthcare providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains, at all times, with the provider.

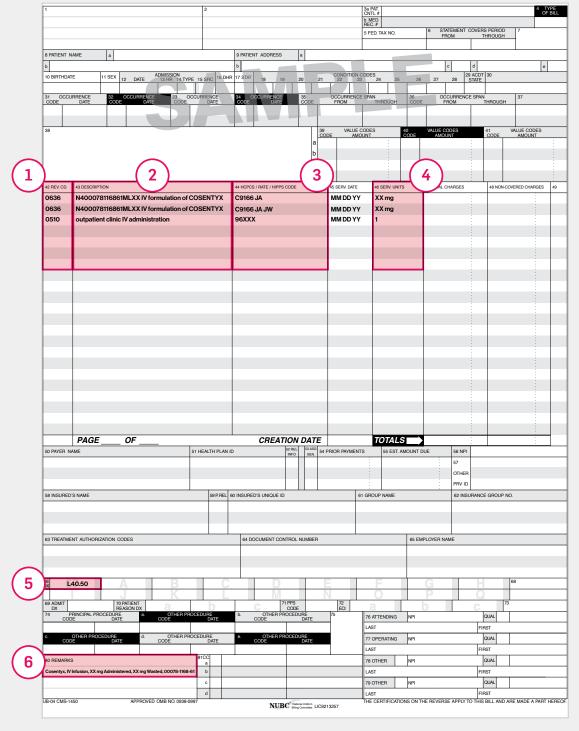
References: 1. Centers for Medicare & Medicaid Services CMS 1500. Accessed July 27, 2023. https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf 2. Codify by AAPC. ICD-10-CM codes lookup. Accessed July 27, 2023. https://www.aapc.com/codes/icd-10-codes-range/#:--:text=TheInternationalClassificationofDiseasesexternalcaus esofinjuries 3. COSENTYX. Prescribing information. Novartis Pharmaceuticals Corp. 4. Centers for Medicare & Medicaid Services. HCPCS quarterly update. Accessed March 13, 2024. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update 5. American Medical Association (AMA). CPT Professional 2023 and E/M Companion 2023 Bundle AMA: 2023.



Submitting claims: sample forms (cont)

Hospital outpatient: sample CMS-1450 (UB-04) form

The IV formulation of COSENTYX® (secukinumab) and the associated services provided in a hospital outpatient setting are billed on the UB-04 claim form or its electronic equivalent. A sample UB-04 form for billing the IV formulation of COSENTYX is provided below.¹ The sample claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party health plans for specific information on their coding, coverage, payment policies, and fee schedules.





Submitting claims: sample forms (cont)

Enter the appropriate revenue code corresponding with the HCPCS code in Box 44.2 Then enter the appropriate revenue code corresponding with the CPT code in Box 44.3,4

Enter a detailed drug or service description for the health plan. When billing for the IV formulation of COSENTYX® (secukinumab), list the N4 indicator first, then the 11-digit NDC number, followed by the unit of measurement qualifier and the unit quantity (Example N400078116861MLXX where "XX" is the number of mL administered or wasted).5 If allowable, noting the IV formulation of COSENTYX can be helpful to the adjudication process.

Box 44

Enter the appropriate HCPCS code (eq. C9166) accompanied by the appropriate modifier as required by the health plan, or if needed based on dose given to patient (please see possible modifiers needed for COSENTYX on page 6).2 Enter the appropriate CPT code (eg, 96XXX).4 Please note, policies may vary in regard to specific code requirements.

Include the appropriate number of billing units. When billing with the product-specific C-code (C9166), 1 billing unit = 1 mg. Please bill according to the amount of product administered or wasted.

Indicate diagnosis using appropriate ICD-10-CM code(s) associated with the claim.⁶

Enter the Drug Name (Cosentyx), Route of Administration (IV Infusion), Dose Administered (mg), Dose Wasted (mg), and 11-digit NDC number. Payers may have varying requirements for data included in Box 80—please check with applicable payer policies to ensure successful submission.

IMPORTANT INFORMATION: The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for those products and services rendered. Providers should contact third-party health plans for specific information on their coding, coverage, and payment policies. Information and materials are provided to assist healthcare providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains, at all times, with the provider.

References: 1. Centers for Medicare & Medicaid Services CMS-1450. Accessed March 13, 2024. https://www.cms.gov/Regulations-and-Guidance/Legislation/ PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450 2. Centers for Medicare & Medicaid Services. HCPCS quarterly update. Accessed July 27, 2023. https://www.cms. gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-quarterly-update 3. Noridian Healthcare Solutions. Revenue codes. Accessed July 25, 2023. https://med.noridianmedicare. com/web/jea/topics/claim-submission/revenue-codes 4. American Medical Association (AMA). CPT Professional 2023 and E/M Companion 2023 Bundle. AMA; 2023. 5. COSENTYX. Prescribing information. Novartis Pharmaceuticals Corp. 6. Codify by AAPC. ICD-10-CM codes lookup. Accessed July 27, 2023. https://www.aapc.com/codes/icd-10-codes-range/#:-:te xt=TheInternationalClassificationofDiseasesexternalcausesofinjuries



Indications & Important Safety Information

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 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 and some fatal infections have been reported in patients treated with COSENTYX.

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.

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.



Indications & Important Safety Information (cont)

WARNINGS AND PRECAUTIONS (cont)

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). 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

Anaphylaxis and cases of urticaria occurred in COSENTYX treated subjects in clinical trials. If an anaphylactic or other serious allergic reaction occurs, administration of COSENTYX should be discontinued immediately and appropriate therapy initiated.

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.



Glossary

CMS-1450 (UB-04) form: Created by the Centers for Medicare & Medicaid Services (CMS), this form is used by healthcare professionals to bill claims for hospital outpatient services.

CMS-1500 form: Created by CMS, this form is used by healthcare professionals to bill claims for in-office patient services.

Current Procedural Terminology (CPT) code: Uniform language for coding medical services and procedures to streamline reporting and increase accuracy and efficiency.

Healthcare Common Procedure Coding System (HCPCS): Identifies the items and services included within certain designated health services (DHS) categories or that may qualify for certain exceptions.

International Classification of Diseases, Tenth Revision (ICD-10) diagnosis code: A system used by physicians to classify and code all diagnoses, symptoms, and procedures for claims processing.

National Drug Code (NDC): Universal product identifier with a unique set of numbers used for human drugs in the US.

Place of Service codes: Also referred to as a Site of Care code, this is a 2-digit code on healthcare professional claims to indicate the setting in which a service was provided. CMS maintains these codes used throughout the healthcare industry.

Site of Care codes: Also referred to as a Place of Service code, this is a 2-digit code on healthcare professional claims to indicate the setting in which a service was provided. CMS maintains these codes used throughout the healthcare industry.

Setting of Service: Where a drug is administered by a healthcare professional, which affects coding and billing requirements.



COSENTYX® Connect Support Services

Designed to make onboarding seamless and efficient for patients and HCPs

Benefits Verification



Investigate coverage obstacles

• Obstacles may include lack of coverage, prior authorization (PA) denial, and step therapy

Facilitate PA process

- Initiate PA requests or letters of appeal through the provider or support the provider to follow up directly regarding the PA status
- Many payers will allow up to 3 levels of appeal of PA denials

Savings Options



As little as \$0 Co-Pay* Offer for eligible, privately insured patients

- Help patients with the cost of **both** the IV formulation of COSENTYX® (secukinumab) and drug administration*
- You can get patients started using the COSENTYX® (secukinumab) Start Form or by signing them up in the <u>Co-Pay Portal</u>
- Once the Explanation of Benefits has been received, you can submit a co-pay claim electronically or by fax

*See Co-Pay Terms & Conditions below.†Certain payers have carve-outs that restrict utilization of manufacturer support programs.



Acquisition Support

Guidance on appropriate distributors and specialty pharmacies

- Help practices understand the authorized distributors available to order the IV formulation of COSENTYX
- · COSENTYX® Connect can also determine if there are any specialty pharmacy requirements

Billing & Coding Support



Support with understanding the relevant reimbursement codes for the IV formulation of COSENTYX

- ${\boldsymbol{\cdot}}$ Our team is here to help your practice understand the appropriate codes
- Our Billing & Coding Guide also provides a comprehensive overview of the available codes

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• HCPs should contact third-party health plans for specific information on their coding, coverage, and payment policies

Get your patients started on the IV formulation of COSENTYX. Visit the Co-Pay Portal to enroll your patients at <u>COSENTYX.opushealth.com</u> or Patients can sign up for the co-pay program directly by calling us at 1-844-COSENTYX (1-844-267-3689).



*Limitations apply. Valid only for those with private insurance. Program provides up to \$16,000 annually for the cost of COSENTYX and up to \$150 per infusion (up to \$1950 annually) for the cost of administration. Co-pay support for infusion administration cost not available in Rhode Island or Massachusetts. Offer not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this program without notice. See complete Terms & Conditions for details. The information herein is provided for educational purposes only. Novartis cannot guarantee health plan coverage or reimbursement. Coverage and reimbursement may vary significantly by plan, patient, and setting of care. It is the sole responsibility of the healthcare provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

 ${\tt COSENTYX} \ {\tt and} \ {\tt the} \ {\tt COSENTYX} \ {\tt logo} \ {\tt are} \ {\tt registered} \ {\tt trademarks} \ {\tt of} \ {\tt Novartis} \ {\tt AG}.$



