Skyrizi® COMPLETE

GUIDE TO **BILLING AND CODING**

Overview of relevant codes

INDICATIONS[1]

Plaque Psoriasis: SKYRIZI is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Psoriatic Arthritis: SKYRIZI is indicated for the treatment of active psoriatic arthritis in adults.

Crohn's Disease: SKYRIZI is indicated for the treatment of moderately to severely active Crohn's disease in adults.

Ulcerative Colitis: SKYRIZI is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

SAFETY CONSIDERATIONS[1]

SKYRIZI is contraindicated in patients with a history of serious hypersensitivity reaction to risankizumab-rzaa or any of its excipients. Serious hypersensitivity reactions, including anaphylaxis, have been reported with use of SKYRIZI. If a serious hypersensitivity reaction occurs, discontinue SKYRIZI and initiate appropriate therapy immediately. SKYRIZI may increase the risk of infection. Instruct patients to report signs or symptoms of clinically important infection during treatment. Should such an infection occur, discontinue SKYRIZI until infection resolves. Evaluate patients for tuberculosis infection prior to initiating treatment with SKYRIZI. Drug-induced liver injury was reported in a patient with Crohn's disease during induction dosing of SKYRIZI. For the treatment of Crohn's disease and ulcerative colitis, evaluate liver enzymes and bilirubin at baseline and during induction (12 weeks). Interrupt treatment with SKYRIZI if drug-induced liver injury is suspected, until this diagnosis is excluded. Avoid use of live vaccines in SKYRIZI patients.

Please see additional Important Safety Information on page 11.

Please click here for full Prescribing Information.

Skyrizi®
risankizumab-rzaa

OVERVIEW OF **RELEVANT DERMATOLOGY AND RHEUMATOLOGY CODES**

ICD-10-CM diagnosis codes[2]

Plaque psoriasis (Ps)

ICD-10-CM code	Description
L40.0	Psoriasis vulgaris
L40.8	Flexural psoriasis
L40.9	Psoriasis, unspecified

Psoriatic arthritis (PsA)

ICD-10-CM code	Description
L40.5	Arthropathic psoriasis
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.59	Other psoriatic arthropathy

Codes are shown for informational purposes only and are not intended to suggest the use of any drug that is inconsistent with FDA approval, or to function as reimbursement or legal advice. Providers should verify codes with third-party payers.

FDA=US Food and Drug Administration; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

Please see Indications and Important Safety Information on page 11.

Please click here for full Prescribing Information.

Skyrizi® COMPLETE

Skyrizi®
risankizumab-rzaa

OVERVIEW OF **RELEVANT GASTROENTEROLOGY CODES**

ICD-10-CM diagnosis codes[2]

Crohn's disease (CD)

ICD-10-CM code	Description
K50.0-K50.019	Crohn's disease of small intestine
K50.1-K50.119	Crohn's disease of large intestine
K50.8-K50.819	Crohn's disease of both small and large intestine
K50.9-50.919	Crohn's disease, unspecified

Ulcerative colitis (UC)

ICD-10-CM code	Description
K51.0-K51.019	Ulcerative (chronic) pancolitis
K51.2-K51.219	Ulcerative (chronic) proctitis
K51.3-K51.319	Ulcerative (chronic) rectosigmoiditis
K51.4-K51.419	Inflammatory polyps of colon
K51.5-K51.519	Left sided colitis
K51.8-K51.919	Other ulcerative colitis or unspecified

HCPCS codes[1,3]

IV Infusion

HCPCS code	Description	Vial size	Dose	HCPCS units for J2327
J2327	Injection, risankizumab-rzaa, Intravenous, 1 mg	600 mg/10 mL	CD: 600 mg UC: 1200 mg	CD: 600 units UC: 1200 units

This product-specific J-Code was effective starting January 1, 2023; for IV induction dosing only.

Codes are shown for informational purposes only and are not intended to suggest the use of any drug that is inconsistent with FDA approval, or to function as reimbursement or legal advice. Providers should verify codes with third-party payers.

FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; IV=intravenous.

Please see Indications and Important Safety Information on page 11.

Please click here for full Prescribing Information.

Skyrizi® COMPLETE

Skyrizi®
risankizumab-rzaa

DOSING AND NATIONAL DRUG CODES (NDC)

How do I provide my patients with SKYRIZI?

- A prescription is required for the SKYRIZI Prefilled Syringe 150 mg/mL, Pen 150 mg/mL, IV infusion 600 mg/10 mL, and SKYRIZI On-Body Injector (OBI) 360 mg/2.4 mL and 180 mg/1.2 mL
- The correct NDC must be used to ensure correct pharmacy dispensation
- To ensure your patient receives the appropriate SKYRIZI delivery device, please select a device type from the Enrollment and Prescription Form or when prescribing electronically

NDC[1]

Electronic data exchange standards usually require the use of an 11-digit NDC. To convert these SKYRIZI 10-digit NDC to an 11-digit NDC, a leading zero is added to the first sequence of numbers (in the case of SKYRIZI, a 0 is added in front of 0074 to create 00074). Check with the payer to confirm the correct code required when billing for SKYRIZI.

INDICATION	SKYRIZI	10-digit NDC	11-digit NDC
Ps/PsA	Pen 150 mg/mL	0074-2100-01	00074-2100-01
	Prefilled Syringe 150 mg/mL	0074-1050-01	00074-1050-01
CD/UC	IV Infusion 600 mg/10 mL (60 mg/mL)	0074-5015-01	00074-5015-01
	On-Body Injector 360 mg/2.4 mL (150 mg/mL)	0074-1070-01	00074-1070-01
	On-Body Injector 180 mg/1.2 mL (150 mg/mL)	0074-1065-01	00074-1065-01

For additional guidance on coding, please refer to the Department of Health and Human Services Evaluation and Management Services Guide available at www.cms.gov

For virtual or in-person support, call your Field Access Specialist, or call 1.877.COMPLETE (1.877.266.7538)

CD=Crohn's disease; IV=intravenous; Ps=plaque psoriasis; PsA=psoriatic arthritis; UC=ulcerative colitis.

SAFETY CONSIDERATIONS[1]

SKYRIZI is contraindicated in patients with a history of serious hypersensitivity reaction to risankizumab-rzaa or any of its excipients. Serious hypersensitivity reactions, including anaphylaxis, have been reported with use of SKYRIZI. If a serious hypersensitivity reaction occurs, discontinue SKYRIZI and initiate appropriate therapy immediately. SKYRIZI may increase the risk of infection. Instruct patients to report signs or symptoms of clinically important infection during treatment. Should such an infection occur, discontinue SKYRIZI until infection resolves. Evaluate patients for tuberculosis infection prior to initiating treatment with SKYRIZI. Drug-induced liver injury was reported in a patient with Crohn's disease during induction dosing of SKYRIZI. For the treatment of Crohn's disease and ulcerative colitis, evaluate liver enzymes and bilirubin at baseline and during induction (12 weeks). Interrupt treatment with SKYRIZI if drug-induced liver injury is suspected, until this diagnosis is excluded. Avoid use of live vaccines in SKYRIZI patients.

Please see Indications and additional Important Safety Information on page 11.

Please click here for full Prescribing Information.

Skyrizi® COMPLETE

Skyrizi®
risankizumab-rzaa

CMS-1500 AND CMS-1450 CODING GUIDE

Considerations when using codes

Healthcare provider services are generally billed using evaluation and management codes, which may be accompanied by prolonged service codes when appropriate.

For additional guidance on the appropriate use of prolonged service codes, please refer to the 2024 CPT® code book.

CMS-1500 and CMS-1450 commercial and Medicare coding[4]*

Procedure type	Code
Office visit, new patient	99202-99205
Office visit, established patient	99211-99215
Prolonged service visit without direct patient contact by the physician or non-physician practitioner	99358, +99359†
Hospital outpatient visit (CMS-1450, Medicare only)	G0463
Computed tomography (CT) scan	72125-72133, 72192-72194, 73200-73202, 73700-73702
Magnetic resonance imaging (MRI)	72141-72158, 72195-72197, 73218-73223, 73718-73723
X-ray imaging	72020-72120, 73000-73140, 73501-73660
Uric acid; blood	84550
Therapeutic, prophylactic, and diagnostic injections, IM/SC injection	96372
For PsA only	
Rheumatoid factor; qualitative	86430
For CD/UC only	
Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	96413
Chemotherapy administration, intravenous infusion technique; each additional hour	+96415
Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	96365
Intravenous infusion, for therapy, prophylaxis, or diagnosis; each additional hour	+96366

***The codes shown are only suggestions. The codes you need may vary by patient.**

†93359 is for each additional 30 minutes after the first hour. Use only in conjunction with 93358.

CPT® is a registered trademark of the American Medical Association.

CD=Crohn's disease; CMS=Centers for Medicare & Medicaid Services; CPT®=Current Procedural Terminology; IM=intramuscular; PsA=psoriatic arthritis; SC=subcutaneous; UC=ulcerative colitis.

Please see Indications and Important Safety Information on page 11.

Please click here for full Prescribing Information.

Skyrizi® COMPLETE

Skyrizi® risankizumab-rzaa

Home infusion CPT® coding for CD/UC[3,4]*

Patients with CD and UC may receive SKYRIZI in a home setting. In this setting, commercial payers reimburse providers separately for services and procedures. The products and services provided in the home setting are billed using the CMS-1500 claim form or its electronic claim equivalent.

This section provides general home infusion coding information for SKYRIZI. Coding for SKYRIZI may vary by commercial payer type and plan type. Contact payers for specific coding requirements for billing SKYRIZI.

Procedure type	Code
Home infusion/specialty drug administration, per visit (up to 2 hours)	99601
Home infusion/specialty drug administration, for each additional hour after 2 hours	+99602
Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	S9379

***The codes shown above are for home infusion only. These will typically be used by the infusion provider.**

Lab support CPT® coding for CD/UC[4]

Procedure type	CPT® code
Hepatic function panel test in which the blood levels of protein, albumin, alkaline phosphatase, bilirubin, and liver enzymes are measured	80076
Lab analysis measuring the amount of total bilirubin in a patient's blood	82247
Analysis measuring the amount of direct bilirubin in a patient's blood	82248

Considerations when using evaluation and management CPT® codes

Healthcare provider services are generally billed using evaluation and management codes, which may be accompanied by prolonged service codes when appropriate.

For additional guidance on the appropriate use of prolonged service codes, please refer to the 2024 CPT® code book.

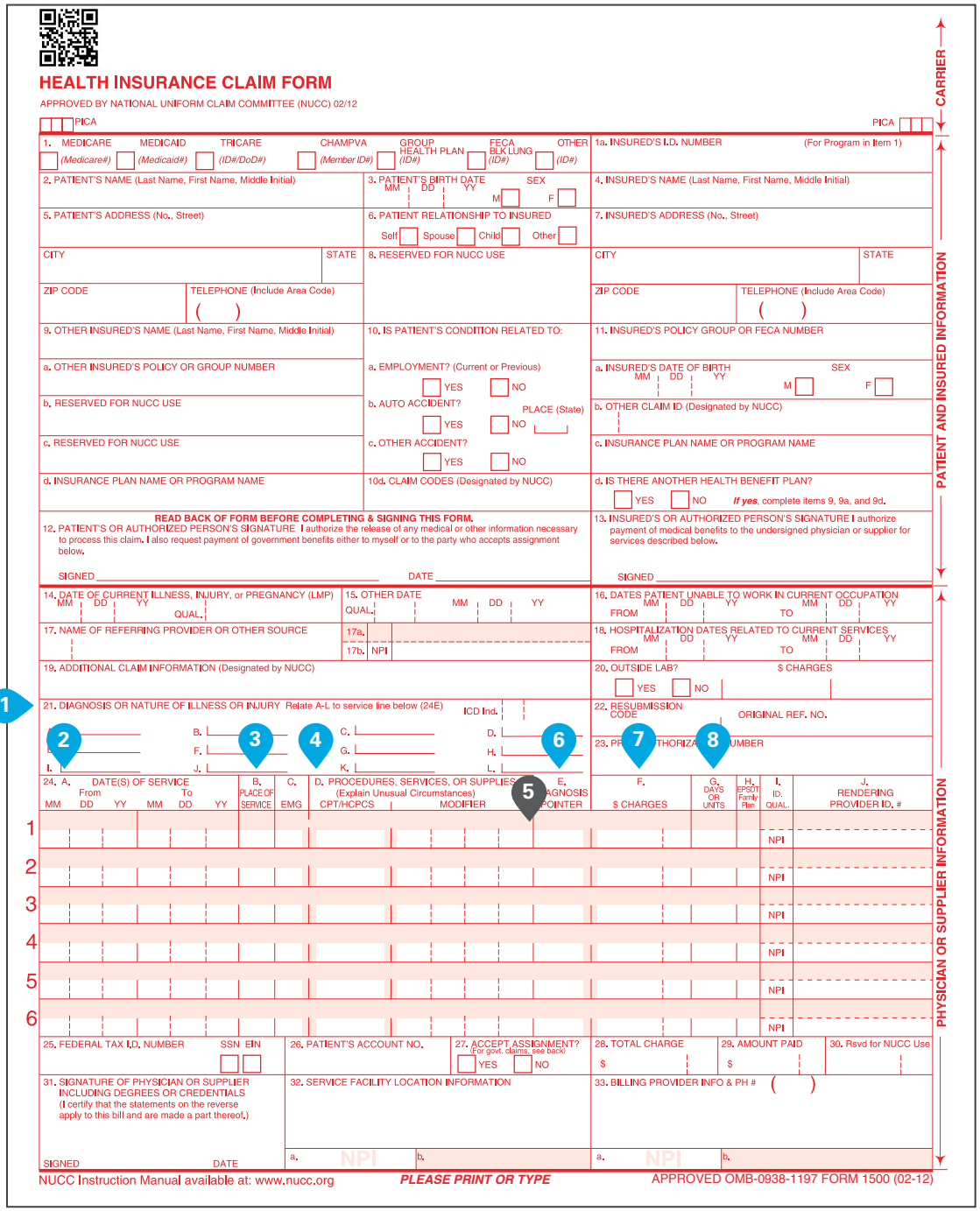
CD=Crohn's disease; CMS=Centers for Medicare & Medicaid Services; CPT®=Current Procedural Terminology; UC=ulcerative colitis.

Please see Indications and Important Safety Information on page 11.

Please click here for full Prescribing Information.

COMPLETING A **CMS-1500 FORM**

Sample CMS-1500 form: use to submit claims to commercial insurance and Medicare for SKYRIZI administered **in your office**



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code)

ZIP CODE TELEPHONE (Include Area Code)

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

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) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

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, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. #

1 NPI

2 NPI

3 NPI

4 NPI

5 NPI

6 NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

1 2 3 4 5 6 7 8

Click here to download a copy of this form

CMS=Centers for Medicare & Medicaid Services.

Please see Indications and Important Safety Information on page 11.

Please click here for full Prescribing Information.

Skyrizi® COMPLETE

Skyrizi®
risankizumab-rzaa

COMPLETING A **CMS-1500 FORM** (CONT'D)

If you are purchasing SKYRIZI from a distributor and need to submit a claim for reimbursement, you can use the CMS-1500 form.

1. **Item 21:** Indicate the diagnosis using the appropriate ICD-10-CM code (see pages 2 and 3 for codes). The "ICD Ind" identifies the ICD-10-CM code set being reported. Enter 0 (zero) as a single digit between the vertical dotted lines.
2. **Item 24A:** If line item NDC information is required, enter it in the shaded portion of Item 24A.
3. **Item 24B:** Enter 11 (in place of a service code for physician offices).
4. **Item 24D CPT/HCPCS:** Indicate appropriate CPT® and HCPCS codes. See pages 3, 5, and 6 of this guide for codes.
5. **Item 24D MODIFIER (Use with CD/UC IV J-code only):** The JA Modifier may be required to indicate intravenous administration. Medicare plans require the JZ Modifier to attest that there was no discarded amount from a single vial. Providers should check with each plan to ensure appropriate coding.

   Specific directions for CD/UC IV infusion:

   - J2327, enter the drug quantity in HCPCS units according to the dose, with 1 mg = 1 unit; each SKYRIZI single-dose vial is 600 mg and equal to 600 units for CD and 1200 units for UC
6. **Item 24E:** Refer to the diagnosis for this service (see Item 21 above). Enter only 1 diagnosis pointer per line.
7. **Item 24F:** Typically, enter average wholesale price (AWP), invoice price, or whichever price method is stated in your contract with the payer.
8. **Item 24G:** Enter the number of units.

   Specific directions for CD/UC IV infusion:

   - 96365: Enter 1 unit for the first hour of infusion
   - 96366: Enter 1 unit for each additional hour of infusion

Reminder: Under certain circumstances, qualified patients may acquire donated or no-cost drugs, or drugs may be covered under a pharmacy benefit and delivered to the administering provider (white bagging). When the drug is supplied by a third party, at no cost to the provider, it should NOT be billed to Medicare or any other payer.

However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it. When reporting drug administration services for free-of-charge drugs, it may be necessary to include drug information on the claim and enter "0.01" charges. Payer policies may vary.

For virtual or in-person support, call your Field Access Specialist, or call 1.877.COMPLETE (1.877.266.7538)

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Providers are encouraged to contact third-party payers for specific information about their coverage policies.

CD=Crohn's disease; CMS=Centers for Medicare & Medicaid Services; CPT®=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; IV=intravenous; NDC=National Drug Code; UC=ulcerative colitis.

Please see Indications and Important Safety Information on page 11.

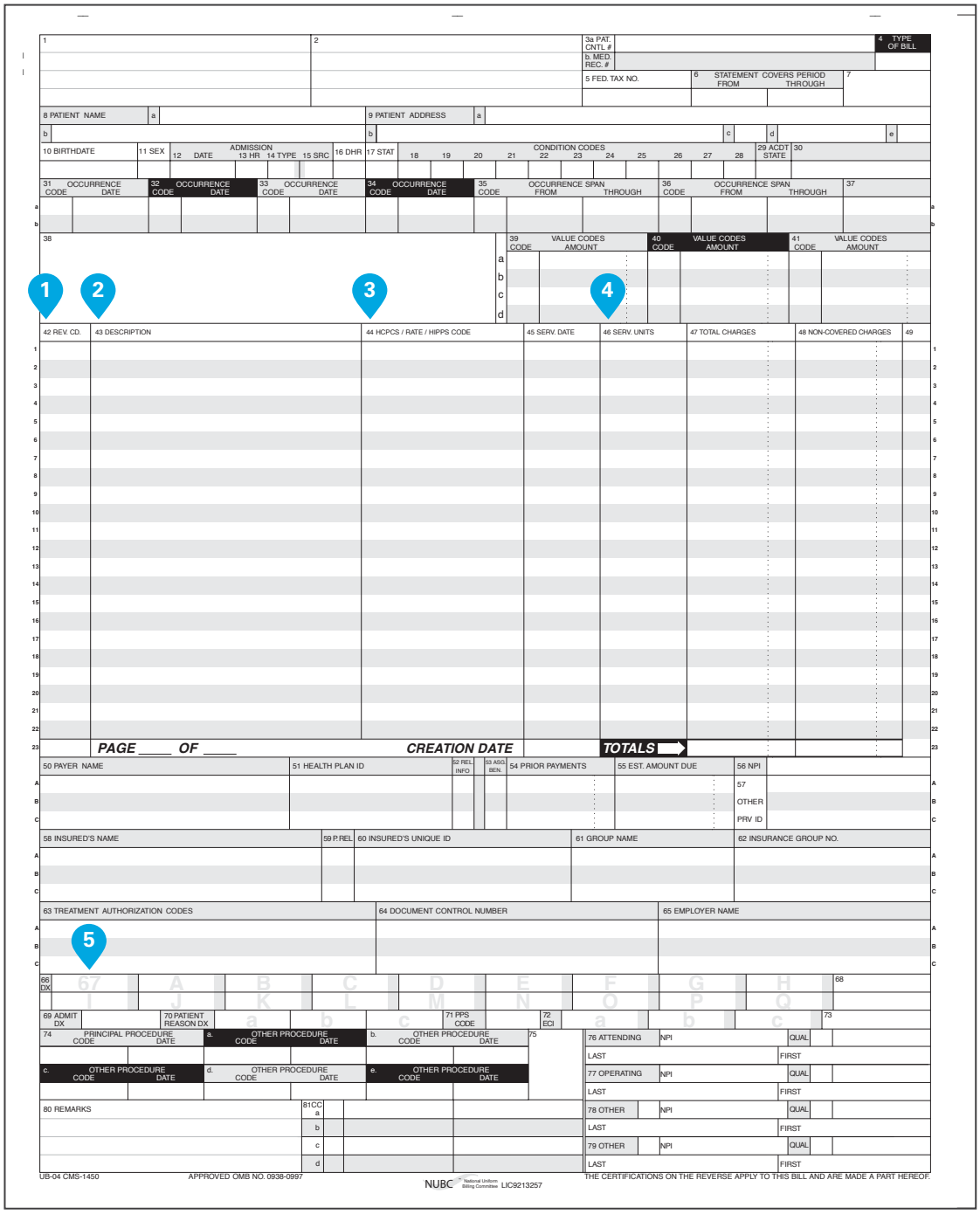
Please click here for full Prescribing Information.

Skyrizi® COMPLETE

Skyrizi®
risankizumab-rzaa

COMPLETING A **CMS-1450 FORM**

Sample CMS-1450 form: use to submit claims to commercial insurance and Medicare for SKYRIZI administered **in a hospital outpatient setting**



Click here to download a copy of this form

CMS=Centers for Medicare & Medicaid Services.

Please see Indications and Important Safety Information on page 11.

Please click here for full Prescribing Information.

Skyrizi® COMPLETE

Skyrizi® risankizumab-rzaa

COMPLETING A **CMS-1450 FORM** (CONT'D)

If you are purchasing SKYRIZI from a distributor and need to submit a claim for reimbursement, you can use the CMS-1450 form.

1. **Locator Box 42:** List revenue codes in ascending order.

2. **Locator Box 43:** Enter narrative description of corresponding revenue code (eg, clinic, lab general). If line item NDC information is required, enter it in the unshaded portions of Locator Box 43. Payer requirements for NDC entries may vary.

3. **Locator Box 44:** Indicate appropriate CPT® and HCPCS codes as required by the payer. See pages 3, 5, and 6 of this guide for codes.

   Specific directions for CD/UC IV infusion:

   - J2327, enter the drug quantity in HCPCS units according to the dose, with 1 mg = 1 unit; each SKYRIZI single-dose vial is 600 mg and equal to 600 units for CD and 1200 units for UC

4. **Locator Box 46:** Enter the number of units.

   Specific directions for CD/UC IV infusion:

   - 96365: Enter 1 unit for the first hour of infusion
   - 96366: Enter 1 unit for each additional hour of infusion

5. **Locator Box 67:** Indicate the diagnosis using the ICD-10-CM code that supports medical justification for Crohn's disease or ulcerative colitis (see page 3 for ICD-10-CM codes).

Reminder: Under certain circumstances, qualified patients may acquire donated or no-cost drugs, or drugs may be covered under a pharmacy benefit and delivered to the administering provider (white bagging). When the drug is supplied by a third party, at no cost to the provider, it should NOT be billed to Medicare or any other payer.

However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it. When reporting drug administration services for free-of-charge drugs, it may be necessary to include drug information on the claim and enter "0.01" charges. Payer policies may vary.

For virtual or in-person support, call your Field Access Specialist, or call 1.877.COMPLETE (1.877.266.7538)

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Providers are encouraged to contact third-party payers for specific information about their coverage policies.

CD=Crohn's disease; CMS=Centers for Medicare & Medicaid Services; CPT®=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; IV=intravenous; NDC=National Drug Code; UC=ulcerative colitis.

Please see Indications and Important Safety Information on page 11.

Please click here for full Prescribing Information.

Skyrizi® COMPLETE

Skyrizi®
risankizumab-rzaa

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR SKYRIZI® (risankizumab-rzaa)

INDICATIONS[1]

Plaque Psoriasis: SKYRIZI is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Psoriatic Arthritis: SKYRIZI is indicated for the treatment of active psoriatic arthritis in adults.

Crohn's Disease: SKYRIZI is indicated for the treatment of moderately to severely active Crohn's disease in adults.

Ulcerative Colitis: SKYRIZI is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

IMPORTANT SAFETY INFORMATION[1]

Hypersensitivity Reactions

SKYRIZI® (risankizumab-rzaa) is contraindicated in patients with a history of serious hypersensitivity reaction to risankizumab-rzaa or any of the excipients. Serious hypersensitivity reactions, including anaphylaxis, have been reported with the use of SKYRIZI. If a serious hypersensitivity reaction occurs, discontinue SKYRIZI and initiate appropriate therapy immediately.

Infection

SKYRIZI may increase the risk of infection. Do not initiate treatment with SKYRIZI in patients with a clinically important active infection until it 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 SKYRIZI. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, closely monitor and discontinue SKYRIZI until the infection resolves.

Tuberculosis (TB)

Prior to initiating treatment with SKYRIZI, evaluate for TB infection and consider treatment in patients with latent or active TB for whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after SKYRIZI treatment. Do not administer SKYRIZI to patients with active TB.

Hepatotoxicity in Treatment of Inflammatory Bowel Disease

Drug-induced liver injury was reported in a patient with Crohn's disease who was hospitalized for a rash during induction dosing of SKYRIZI. For the treatment of Crohn's disease and ulcerative colitis, evaluate liver enzymes and bilirubin at baseline and during induction (12 weeks); monitor thereafter according to routine patient management. Consider an alternate treatment for patients with evidence of liver cirrhosis. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct your patient to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Administration of Vaccines

Avoid use of live vaccines in patients treated with SKYRIZI. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. Prior to initiating SKYRIZI, complete all age-appropriate vaccinations according to current immunization guidelines.

Adverse Reactions

Most common (≥1%) adverse reactions associated with SKYRIZI in plaque psoriasis and psoriatic arthritis include upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections.

In psoriatic arthritis phase 3 trials, the incidence of hepatic events was higher with SKYRIZI compared to placebo.

Most common (>3%) adverse reactions associated with SKYRIZI in Crohn's disease are upper respiratory infections, headache, and arthralgia in induction, and arthralgia, abdominal pain, injection site reactions, anemia, pyrexia, back pain, arthropathy, and urinary tract infection in maintenance.

Most common (≥3%) adverse reactions associated with SKYRIZI in ulcerative colitis are arthralgia in induction, and arthralgia, pyrexia, injection site reactions, and rash in maintenance.

Lipid Elevations: Increases from baseline and increases relative to placebo were observed at Week 4 and remained stable to Week 12 in patients treated with SKYRIZI in Crohn's disease. Lipid elevations observed in patients with ulcerative colitis were similar to those in Crohn's disease.

Dosage Forms and Strengths: SKYRIZI (risankizumab-rzaa) is available in a 150 mg/mL prefilled syringe and pen, a 600 mg/10 mL single-dose vial for intravenous infusion, and a 180 mg/1.2 mL or 360 mg/2.4 mL single-dose prefilled cartridge with on-body injector.

References: 1. SKYRIZI [package insert]. North Chicago, IL: AbbVie Inc. **2.** Centers for Medicare & Medicaid Services. 2024 ICD-10-CM. 2024 Code Tables, Tabular and Index. Updated February 1, 2024. Accessed February 21, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm **3.** Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) quarterly update. Centers for Medicare and Medicaid Services website. Accessed April 9, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **4.** American Medical Association. Current Procedural Terminology: CPT® 2024: Professional Edition. Chicago, IL: AMA Press; 2023.

Please click here for full Prescribing Information.

abbvie

US-SKZG-240268 June 2024

Skyrizi®
risankizumab-rzaa