Selarsdi™
(ustekinumab-aekn)
Injection • 45mg/0.5mL • 90mg/mL

BILLING AND CODING GUIDE FOR SELARSDI™ (USTEKINUMAB-AEKN) INJECTION

Using this billing and coding guide

This guide is intended for informational purposes only, and not intended to take the place of the healthcare provider's diagnosis and treatment decisions. Healthcare providers are responsible for the accuracy, legitimacy, and completeness of any claims, invoices, and other documentation supplied to payers. Healthcare providers should contact the payer for answers to specific questions about payment or coverage. Specific direction from the payer supersedes the codes included here. Using the codes listed in this guide does not guarantee reimbursement.

INDICATIONS

SELARSDI™ (ustekinumab-aekn) Injection, is a human interleukin-12 and -23 antagonist indicated for:

- the treatment of adults and pediatric patients 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- the treatment of adults and pediatric patients 6 years of age and older with active psoriatic arthritis.
- the treatment of adult patients with moderately to severely active Crohn's disease.
- the treatment of adult patients with moderately to severely active ulcerative colitis.

IMPORTANT SAFETY INFORMATION

SELARSDI™ (ustekinumab-aekn) Injection is contraindicated in patients with clinically significant hypersensitivity to ustekinumab products or to any of the excipients in SELARSDI.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

teva Biosimilars

Table of contents

Selarsdi™ (ustekinumab-aekn)
Injection · 45mg/0.5mL · 90mg/mL

IMPORTANT SAFETY INFORMATION

Infections

Ustekinumab products may increase the risk of infections and reactivation of latent infections. Serious bacterial, mycobacterial, fungal, and viral infections were observed in patients receiving ustekinumab products. Serious infections requiring hospitalization or otherwise clinically significant infections were reported. In patients with plaque psoriasis, these included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis, and urinary tract infections. In patients with psoriatic arthritis, this included cholecystitis. In patients with Crohn's disease, these included anal abscess, gastroenteritis, ophthalmic herpes zoster, pneumonia, and Listeria meningitis. In patients with ulcerative colitis, these included gastroenteritis, ophthalmic herpes zoster, pneumonia, and listeriosis.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Available formulations of SELARSDI™ (ustekinumab-aekn) injection[1]

Selarsdi™
(ustekinumab-aekn)
Injection · 45mg/0.5mL · 90mg/mL

Dose: 45 mg/0.5 mL | Dose: 90 mg/mL

This guide includes coding for the single-dose prefilled syringe for subcutaneous use.

Dose: 130 mg/26 mL (5 mg/mL) vial

This guide includes coding for the single-dose vial for intravenous (IV) infusion.

Use HCPCS code Q9998 for all formulations of SELARSDI[2]

IMPORTANT SAFETY INFORMATION (cont'd)

Infections (cont'd)

Treatment with SELARSDI should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to initiating use of SELARSDI 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 while on treatment with SELARSDI and discontinue SELARSDI for serious or clinically significant infections until the infection resolves or is adequately treated.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Selarsdi™
(ustekinumab-aekn)
Injection · 45mg/0.5mL · 90mg/mL

Billing and coding guidance for SELARSDI

Intravenous (IV) use: Induction

Crohn's disease and ulcerative colitis

IMPORTANT SAFETY INFORMATION (cont'd)

Theoretical Risk for Vulnerability to Particular Infections

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria (including nontuberculous, environmental mycobacteria), Salmonella (including nontyphi strains), and Bacillus Calmette-Guerin (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients. It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with ustekinumab products may be susceptible to these types of infections. Consider diagnostic testing, eg, tissue culture, stool culture, as dictated by clinical circumstances.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

SELARSDI intravenous (IV) use: Induction[1]

Selarsdi™ (ustekinumab-aekn)
Injection · 45mg/0.5mL · 90mg/mL

Indication

SELARSDI is indicated for the treatment of adult patients with moderately to severely active Crohn's disease or moderately to severely active ulcerative colitis.

Dosing

SELARSDI is administered in 2 phases: induction and maintenance for the treatment of Crohn's disease or ulcerative colitis.

The following section summarizes billing and coding for the **induction dose,** provided as a **single intravenous infusion using weight-based dosing.**

SELARSDI IV weight-based dosage regimen

Patient weight range	Dose	Number of 130 mg/26 mL vials
55 kg or less	260 mg	2 vials
More than 55 kg to 85 kg	390 mg	3 vials
More than 85 kg	520 mg	4 vials

IMPORTANT SAFETY INFORMATION (cont'd)

Pre-Treatment Evaluation of Tuberculosis (TB)

Evaluate patients for TB prior to initiating treatment with SELARSDI. Do not administer SELARSDI to patients with active TB infection. Initiate treatment of latent TB before administering SELARSDI. Consider anti-tuberculosis therapy prior to initiation of SELARSDI in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients receiving SELARSDI for signs and symptoms of active TB during and after treatment.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Billing codes

Selarsdi™ (ustekinumab-aekn)
Injection • 45mg/0.5mL • 90mg/mL

Diagnosis codes

The ICD-10-CM diagnosis code ranges are provided only as an example of potentially relevant codes. Providers should select the most appropriate diagnosis code(s) with the highest level of specificity to describe a patient's actual condition.

ICD-10 CM codes[3]

Code range	Description
K50.00 – K50.919	Crohn's disease
K51.00 – K51.919	Ulcerative colitis

This information should not be construed to suggest a diagnosis as all diagnostic decisions and coding are solely the province of the treating provider.

ICD-10 CM = International Classification of Diseases, 10th Revision, Clinical Modification

National Drug Code (NDC)[1,4,5]

10-digit NDC	11-digit NDC[a]	Description
51759-708-13	51759-0708-13	130 mg/26 mL (5 mg/mL) vial Single-use vial containing 130 mg (26 mL) of ustekinumab for IV infusion

[a]Payer requirements regarding use of a 10-digit or 11-digit NDC may vary. Note that the product's NDC has been "zero-filled" (underlined) to ensure the creation of an 11-digit code that meets CMS standards.

NDC units[1,5]

NDC units dispensed are based on the packaging and numeric quantity administered to the patient. The following is an example for the 390 mg dose of SELARSDI.

Billing dose	NDC billing units	NDC (11-digit)	Packaging	NDC unit of measure
390 mg	78	51759-0708-13	130 mg/26 mL vial (liquid)	ML

It is important to follow payer instructions for billing NDC units including[4,5]:

- The use of necessary qualifiers (eg, N4 and ML)
- Reporting a 10- or 11-digit NDC
- Reporting the correct number of NDC units administered

IMPORTANT SAFETY INFORMATION (cont'd)

Malignancies

Ustekinumab products are immunosuppressants and may increase the risk of malignancy. Malignancies were reported among patients who received ustekinumab in clinical trials. The safety of ustekinumab products has not been evaluated in patients who have a history of malignancy or who have a known malignancy. There have been post-marketing reports of the rapid appearance of multiple cutaneous

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Billing codes (cont'd)

Selarsdi™ (ustekinumab-aekn)
Injection · 45mg/0.5mL · 90mg/mL

HCPCS level II code[2,6]

Code	Description
Q9998	Injection, ustekinumab-aekn (selarsdi), 1 mg

HCPCS = Healthcare Common Procedure Coding System

Important: When billing for drugs that have one HCPCS level II code but multiple routes of administration, the use of the JA and JB modifiers is generally required.

Modifier	Description
JA	Intravenous administration
JB	Subcutaneous administration

Use modifier JA (intravenous administration) when billing for the induction IV infusion.

HCPCS billing units[1,7]

Number of vials	Total dose	Number of billing units[b]
1	130 mg	130
2	260 mg	260
3	390 mg	390
4	520 mg	520

[b]Each 1 mg dose of SELARSDI equals 1 billing unit.

CPT® code[3]

Code	Description
96365	Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour

CPT® = Current Procedural Terminology

Always confirm with payers as policies vary on their required codes used to describe infusion services.

IMPORTANT SAFETY INFORMATION (cont'd)

Malignancies (cont'd)

squamous cell carcinomas in patients receiving ustekinumab products who had pre-existing risk factors for developing non-melanoma skin cancer (NMSC). All patients receiving SELARSDI, especially those greater than 60 years of age or those with a history of Psoralen plus ultraviolet A (PUVA) or prolonged immunosuppressant treatment, should be monitored for the appearance of NMSC.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Additional coding for consideration

Selarsdi™ (ustekinumab-aekn)
Injection • 45mg/0.5mL • 90mg/mL

The following is a sampling of common modifiers and other codes that may be required for billing for SELARSDI and are not an exhaustive list. As always, it is important to check with individual payers as policies and billing requirements vary.

HCPCS and CPT® modifiers[6,8,9]

Modifier	Description
25	Significant, separately identifiable evaluation and management (E/M) service by the same physician or other qualified healthcare professional on the same day of the procedure or other service
PO	Excepted services provided at an off-campus, outpatient, provider-based department of a hospital
PN	Non-excepted service provided at an off campus, outpatient, provider-based department of a hospital
JA	Intravenous administration
JB	Subcutaneous administration
JW	Drug amount discarded/not administered to any patient[c]
JZ	Zero drug amount discarded/not administered to any patient[c]
JG	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes
TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities

[c]Required for Medicare claims.

Place of service codes for CMS-1500 claims[10]

Code	Description
11	Office
19	Off campus – outpatient hospital
22	On campus – outpatient hospital

Revenue codes for CMS-1450 (UB-04) claims[11]

Code	Description
0260	IV Therapy, general
0636	Pharmacy, drugs requiring detailed coding
0940	Other therapeutic services, general

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions

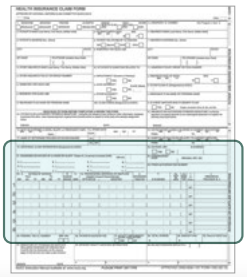
Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with ustekinumab products. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue SELARSDI.

Posterior Reversible Encephalopathy Syndrome (PRES)

Two cases of posterior reversible encephalopathy syndrome (PRES), also known as Reversible Posterior Leukoencephalopathy Syndrome (RPLS), were reported in clinical trials. Cases have also been reported in postmarketing experience in patients with psoriasis, psoriatic arthritis, and Crohn's disease. Clinical presentation included headaches, seizures, confusion, visual disturbances, and imaging changes consistent with PRES a few days to several months after ustekinumab product initiation. A few cases reported latency of a year

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Sample CMS-1500 claim form[2-4,6,7,12]



Healthcare providers who administer SELARSDI to patients should submit manual claims on the CMS-1500 claim form. The following is sample coding for submitting a manual claim for SELARSDI using a 390 mg IV induction dose.

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? ☐ YES ☐ NO $ CHARGES

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

A. K51.00 B. C. D.

E. F. H.

I. J. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

24B 24D 24E 24F 24G

24A

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 N4 51759070813ML78 MM DD YY		11		Q9998	JA JZ	A		390		NPI	
2 MM DD YY		11		96365		A		1		NPI	
3										NPI	

SUPPLIER INFO

See page 8 for descriptions of additional coding that may be required on claims.

Item 21 **Diagnosis or nature of illness or injury:** Enter the appropriate ICD-10-CM diagnosis code(s) on each line

Item 24A **Date(s) of service:** Enter date(s) of service and provide applicable qualifiers in shaded line if required by the payer. If the NDC and NDC units are required by payer, enter in the shaded portion of line above dates of service

Item 24B **Place of service:** Enter the appropriate place of service code

Item 24D **Procedures, services, or supplies:** Enter the CPT® or HCPCS code(s) and modifier(s) as required by payers

Example:

Line 1: Q9998 – Injection, ustekinumab-aekn (selarsdi), 1 mg
Line 2: 96365 – CPT® code for administration: Intravenous infusion

Line 1: JA – Modifier to indicate intravenous administration
JZ – Modifier to attest that there was no drug amount discarded

Item 24E **Diagnosis pointer:** Enter the diagnosis code reference letter (A-L)

Item 24F **Charges:** Enter the total charges for each service

Item 24G **Days or units:** Enter the number of units related to the service or product

SELARSDI HCPCS units:

One 130 mg vial = 130 units | Two 130 mg vial = 260 units | Three 130 mg vials = 390 units | Four 130 mg vials = 520 units

IMPORTANT SAFETY INFORMATION (cont'd)

Posterior Reversible Encephalopathy Syndrome (PRES) (cont'd)

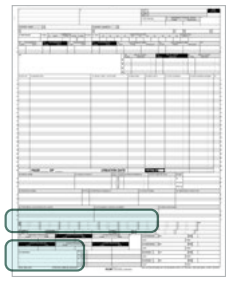
or longer. Patients recovered with supportive care following withdrawal of ustekinumab products.

Monitor all patients treated with SELARSDI for signs and symptoms of PRES. If PRES is suspected, promptly administer appropriate treatment and discontinue SELARSDI.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Sample CMS-1450 (UB-04) claim form[2,3,5-7,13,14]

Institutional healthcare providers who administer SELARSDI to patients should submit manual claims on the CMS-1450 (UB-04) claim form. The following is sample coding for submitting a manual claim for SELARSDI using a 390 mg IV induction dose.



42	43	44	45	46	47
42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES
1 0260	IV Therapy	96365		1	
2 0636	SELARSDI	Q9998 JA		390	

67
66 DX: K51.00
69 ADMIT DX
70 PATIENT REASON DX

See page 8 for descriptions of additional coding that may be required on claims.

FL 42 **Revenue code:** List revenue codes in ascending order

FL 43 **Revenue description:** Enter narrative description for corresponding revenue code. If the NDC and NDC units are required by the payer, they should be entered here in the requested format (eg, N4 and ML qualifiers)

FL 44 **HCPCS codes:** Enter the CPT® or HCPCS code(s) and modifier(s) as required by payers

Example:
Line 1: 96365 – CPT® code for administration: Intravenous infusion
Line 2: Q9998 – Injection, ustekinumab-aekn (selarsdi), 1 mg
Line 2: JA – Modifier to indicate intravenous administration

FL 46 **Service units:** Enter the number of units related to the service or product

SELARSDI HCPCS units:

- One 130 mg vial = 130 units
- Two 130 mg vial = 260 units
- Three 130 mg vials = 390 units
- Four 130 mg vials = 520 units

FL 47 **Charges:** Enter the total charges for each service

FL 67 **Diagnosis:** Enter the appropriate ICD-10-CM diagnosis code. Additional diagnoses should be included in form locator 67-A-Q

IMPORTANT SAFETY INFORMATION (cont'd)

Immunizations

Prior to initiating therapy with SELARSDI, patients should receive all age-appropriate immunizations as recommended by current immunization guidelines. Patients being treated with SELARSDI should not receive live vaccines. Avoid administering BCG vaccines during treatment with SELARSDI or for one year

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Selarsdi™
(ustekinumab-aekn)
Injection · 45mg/0.5mL · 90mg/mL

Billing and coding guidance for SELARSDI

Subcutaneous injection: Maintenance dose

Crohn's disease and ulcerative colitis

IMPORTANT SAFETY INFORMATION (cont'd)

Immunizations (cont'd)

prior to initiating treatment or one year following discontinuation of treatment. Caution is advised when administering live vaccines to household contacts of patients receiving SELARSDI because of the potential risk for shedding from the household contact and transmission to patient. Non-live vaccinations received during a course of SELARSDI may not elicit an immune response sufficient to prevent disease.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

SELARSDI subcutaneous injection: Maintenance dose[1]

Selarsdi™ (ustekinumab-aekn)
Injection · 45mg/0.5mL · 90mg/mL

Indication

SELARSDI is indicated for the treatment of adult patients with moderately to severely active Crohn's disease or moderately to severely active ulcerative colitis.

Dosing

SELARSDI is administered in 2 phases: induction and maintenance for the treatment of Crohn's disease or ulcerative colitis.

There is one formulation for the maintenance dosage regimen and should be used for subcutaneous injection ONLY:

- 90 mg/mL single-dose prefilled syringe

The following section summarizes billing and coding for the **maintenance dose,** when administered using the **90 mg/mL single-dose prefilled syringe.**

Recommended SELARSDI maintenance dosage

Dose	Frequency
90 mg	8 weeks after initial IV dose; every 8 weeks thereafter

IMPORTANT SAFETY INFORMATION (cont'd)

Concomitant Therapies

The safety of ustekinumab products, in combination with other biologic immunosuppressive agents or phototherapy has not been evaluated in clinical trials of psoriasis. Ultraviolet-induced skin cancers developed earlier and more frequently in mice. In psoriasis studies, the relevance of findings in mouse models for malignancy risk in humans is unknown. In psoriatic arthritis studies, concomitant methotrexate use did not appear to influence the safety or efficacy of ustekinumab.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Billing codes

Selarsdi™ (ustekinumab-aekn)
Injection • 45mg/0.5mL • 90mg/mL

Diagnosis codes

The ICD-10-CM diagnosis code ranges are provided only as an example of potentially relevant codes. Providers should select the most appropriate diagnosis code(s) with the highest level of specificity to describe a patient's actual condition.

ICD-10 CM codes[3]

Code range	Description
K50.00 – K50.919	Crohn's disease
K51.00 – K51.919	Ulcerative colitis

This information should not be construed to suggest a diagnosis as all diagnostic decisions and coding are solely the province of the treating provider.

ICD-10 CM = International Classification of Diseases, 10th Revision, Clinical Modification

National Drug Code (NDC)[1,4,5]

10-digit NDC	11-digit NDC[d]	Description
51759-607-32	51759-0607-32	90 mg/mL single-dose prefilled syringe

[d]Payer requirements regarding use of a 10-digit or 11-digit NDC may vary. Note that the product's NDC has been "zero-filled" (underlined) to ensure the creation of an 11-digit code that meets CMS standards.

NDC units[1,5]

NDC units dispensed are based on the packaging and numeric quantity administered to the patient. The following is an example for the 90 mg dose of SELARSDI.

Billing dose	NDC billing units	NDC (11-digit)	Packaging	NDC unit of measure
90 mg	1	51759-0607-32	90 mg/mL prefilled syringe	ML

It is important to follow payer instructions for billing NDC units including[4,5]:

- The use of necessary qualifiers (eg, N4 and ML)
- Reporting a 10- or 11-digit NDC
- Reporting the correct number of NDC units administered

IMPORTANT SAFETY INFORMATION (cont'd)

Noninfectious Pneumonia

Cases of interstitial pneumonia, eosinophilic pneumonia, and cryptogenic organizing pneumonia have been reported during post-approval use of ustekinumab products. Clinical presentations included cough, dyspnea, and interstitial infiltrates following one to three doses. Serious outcomes have included respiratory failure and prolonged hospitalization. Patients improved with discontinuation of therapy and, in certain cases, administration of corticosteroids. If diagnosis is confirmed, discontinue SELARSDI and institute appropriate treatment.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Billing codes (cont'd)

Selarsdi™ (ustekinumab-aekn)
Injection · 45mg/0.5mL · 90mg/mL

HCPCS level II code[2,6]

Code	Description
Q9998	Injection, ustekinumab-aekn (selarsdi), 1 mg

HCPCS = Healthcare Common Procedure Coding System

Important: When billing for drugs that have one HCPCS level II code but multiple routes of administration, the use of the JA and JB modifiers is generally required.

Modifier	Description
JA	Intravenous administration
JB	Subcutaneous administration

Use modifier JB (subcutaneous administration) when billing for the maintenance subcutaneous injection of the 90 mg prefilled syringe.

HCPCS billing units[1,7]

Total dose	Packaging	Number of billing units[e]
90 mg	90 mg/mL single-dose prefilled syringe	90

[e]Each 1 mg dose of SELARSDI equals 1 billing unit.

CPT® code[3]

Code	Description
96372	Therapeutic, prophylactic, or diagnostic injection; subcutaneous injection or intramuscular

CPT® = Current Procedural Terminology

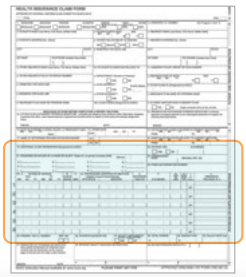
IMPORTANT SAFETY INFORMATION (cont'd)

Allergen Immunotherapy

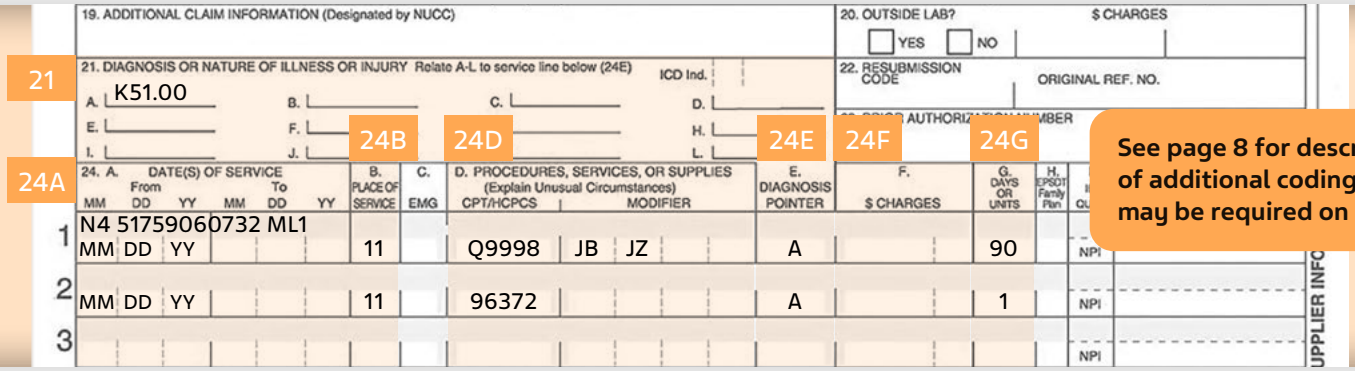
Ustekinumab products have not been evaluated in patients who have undergone allergy immunotherapy. Ustekinumab products may decrease the protective effect of allergen immunotherapy (decrease tolerance) which may increase the risk of an allergic reaction to a dose of allergen immunotherapy. Therefore, caution should be exercised in patients receiving or who have received allergen immunotherapy, particularly for anaphylaxis.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Sample CMS-1500 claim form[2-4,6,7,12]



Healthcare providers who administer SELARSDI to patients should submit manual claims on the CMS-1500 claim form. The following is sample coding for submitting a manual claim for SELARSDI 90 mg/mL prefilled syringe for subcutaneous injection maintenance dosing.



See page 8 for descriptions of additional coding that may be required on claims.

Item 21 **Diagnosis or nature of illness or injury:** Enter the appropriate ICD-10-CM diagnosis code(s) on each line

Item 24A **Date(s) of service:** Enter date(s) of service and provide applicable qualifiers in shaded line if required by the payer. If the NDC and NDC units are required by payer, enter in the shaded portion of line above dates of service

Item 24B **Place of service:** Enter the appropriate place of service code

Item 24D **Procedures, services, or supplies:** Enter the CPT® or HCPCS code(s) and modifier(s) as required by payers

Example:

Line 1: Q9998 – Injection, ustekinumab-aekn (selarsdi), 1 mg
JB – Modifier to indicate subcutaneous administration
JZ – Modifier to attest that there was no drug amount discarded

Line 2: 96372 – CPT® code for drug administration: subcutaneous injection or intramuscular

Item 24E **Diagnosis pointer:** Enter the diagnosis code reference letter (A-L)

Item 24F **Charges:** Enter the total charges for each service

Item 24G **Days or units:** Enter the number of units related to the service or product

SELARSDI HCPCS units: 90 mg = 90 units

IMPORTANT SAFETY INFORMATION (cont'd)

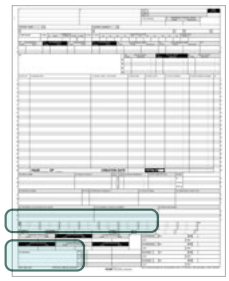
Most Common Adverse Reactions

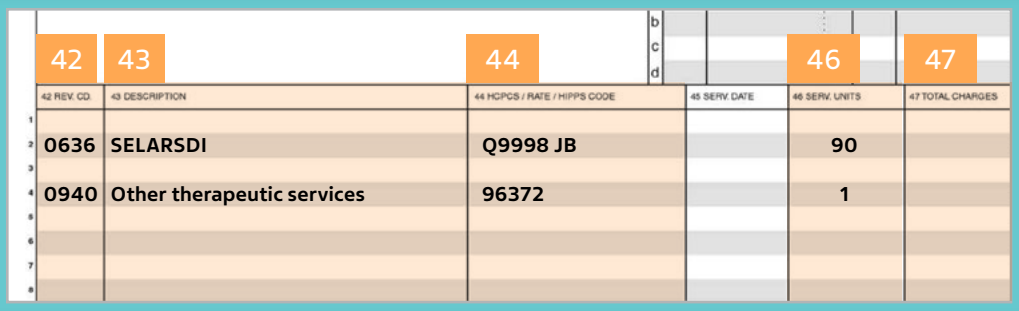
The most common adverse reactions for plaque psoriasis (≥3%) were nasopharyngitis, upper respiratory tract infection, headache, and fatigue. The safety profile in pediatric patients with plaque psoriasis was similar to that of adults with plaque psoriasis. The most common adverse reaction for Crohn's disease

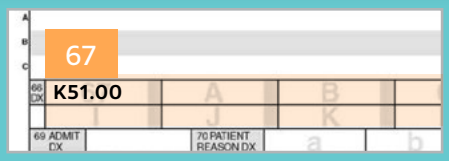
Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Sample CMS-1450 (UB-04) claim form[2,3,5-7,13,14]

Institutional healthcare providers who administer SELARSDI to patients should submit manual claims on the CMS-1450 (UB-04) claim form. The following is sample coding for submitting a manual claim for SELARSDI 90 mg/mL prefilled syringe for subcutaneous injection maintenance dosing.







See page 8 for descriptions of additional coding that may be required on claims.

FL 42 **Revenue code:** List revenue codes in ascending order

FL 43 **Revenue description:** Enter narrative description for corresponding revenue code. If the NDC and NDC units are required by the payer, they should be entered here in the requested format (eg, N4 and ML qualifiers)

FL 44 **HCPCS codes:** Enter the CPT® or HCPCS code(s) and modifier(s) as required by payers

Example:

Line 1: Q9998 – Injection, ustekinumab-aekn (selarsdi), 1 mg
JB – Modifier to indicate subcutaneous administration

Line 2: 96372 – CPT® code for drug administration: subcutaneous injection or intramuscular

FL 46 **Service units:** Enter the number of units related to the service or product

SELARSDI HCPCS units: 90 mg = 90 units

FL 47 **Charges:** Enter the total charges for each service

FL 67 **Diagnosis:** Enter the appropriate ICD-10-CM diagnosis code. Additional diagnoses should be included in form locator 67-A-Q

IMPORTANT SAFETY INFORMATION (cont'd)

Most Common Adverse Reactions (cont'd)

induction (≥3%) was vomiting. The most common adverse reactions for Crohn's disease maintenance (≥3%) were nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus,

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Selarsdi™
(ustekinumab-aekn)
Injection · 45mg/0.5mL · 90mg/mL

Billing and coding guidance for SELARSDI

Prefilled syringe for subcutaneous injection

Plaque psoriasis and psoriatic arthritis

IMPORTANT SAFETY INFORMATION (cont'd)

Most Common Adverse Reactions (cont'd)

urinary tract infection, and sinusitis. The most common adverse reaction for ulcerative colitis induction (≥3%) was nasopharyngitis. The most common adverse reactions for ulcerative colitis maintenance (≥3%) were nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

SELARSDI prefilled syringe for subcutaneous injection[1]

Selarsdi™ (ustekinumab-aekn)
Injection • 45mg/0.5mL • 90mg/mL

Indication

- Treatment of adults and pediatric patients 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Treatment of adults and pediatric patients 6 years of age and older with active psoriatic arthritis

Dosing

Dosing may be weight-based. Induction and maintenance doses are administered by subcutaneous injection.

There are 2 available formulations of SELARSDI for subcutaneous injection:

- 45 mg/0.5 mL single-dose prefilled syringe
- 90 mg/mL single-dose prefilled syringe

The following section summarizes billing and coding for the induction or maintenance subcutaneous injection of the **prefilled syringe.**

SELARSDI subcutaneous injection dosing

Indication	Patient weight	Induction	Maintenance
Plaque psoriasis *Adult*	100 kg or less	45 mg	45 mg at 4 weeks after initial dose then 45 mg every 12 weeks
	More than 100 kg	90 mg	90 mg at 4 weeks after initial dose then 90 mg every 12 weeks
Plaque psoriasis *Pediatric patients (6-17 years old)*	60 kg – 100 kg	45 mg	45 mg at 4 weeks after initial dose then 45 mg every 12 weeks
	More than 100 kg	90 mg	90 mg at 4 weeks after initial dose then 90 mg every 12 weeks
Psoriatic arthritis	All adult patients (see exception below)	45 mg	45 mg at 4 weeks after initial dose then 45 mg every 12 weeks
	Patients with co-existent moderate-to-severe plaque psoriasis weighing more than 100 kg	90 mg	90 mg at 4 weeks after initial dose then 90 mg every 12 weeks

IMPORTANT SAFETY INFORMATION (cont'd)

Infections

Ustekinumab products may increase the risk of infections and reactivation of latent infections. Serious bacterial, mycobacterial, fungal, and viral infections were observed in patients receiving ustekinumab products. Serious infections requiring hospitalization or otherwise clinically significant infections were

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Billing codes

Selarsdi™ (ustekinumab-aekn)
Injection • 45mg/0.5mL • 90mg/mL

Diagnosis codes[3]

The following ICD-10 CM codes may be used when communicating appropriate diagnoses to payers.

ICD-10 CM code	Description
Psoriatic arthritis	
L40.50	Arthropathic psoriasis, unspecified
L40.59	Other psoriatic arthropathy
Psoriasis	
L40.0	Psoriasis vulgaris
L40.9	Psoriasis, unspecified

This information should not be construed to suggest a diagnosis as all diagnostic decisions and coding are solely the province of the treating provider.

ICD-10 CM = International Classification of Diseases, 10th Revision, Clinical Modification

National Drug Code (NDC)[1,5]

10-digit NDC	11-digit NDC[f]	Description
51759-505-32	51759-0505-32	45 mg/0.5 mL single-dose prefilled syringe
51759-607-32	51759-0607-32	90 mg/mL single-dose prefilled syringe

[f]Payer requirements regarding use of a 10-digit or 11-digit NDC may vary. Note that the product's NDC has been "zero-filled" (underlined) to ensure the creation of an 11-digit code that meets CMS standards.

NDC units[1,5]

NDC units dispensed are based on the packaging and numeric quantity administered to the patient. The following are examples for 45 mg and 90 mg doses of SELARSDI.

Billing dose	NDC billing units	NDC (11-digit)	Packaging	NDC unit of measure
45 mg	0.5	51759-0505-32	45 mg/0.5mL single-dose prefilled syringe	ML
90 mg	1	51759-0607-32	90 mg/mL single-dose prefilled syringe	ML

It is important to follow payer instructions for billing NDC units including[4,5]:

- The use of necessary qualifiers (eg, N4 and ML)
- Reporting a 10- or 11-digit NDC
- Reporting the correct number of NDC units administered

IMPORTANT SAFETY INFORMATION (cont'd)

Infections (cont'd)

reported. In patients with plaque psoriasis, these included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis, and urinary tract infections. In patients with psoriatic arthritis, this included cholecystitis. In patients with Crohn's disease, these included anal abscess, gastroenteritis, ophthalmic herpes zoster, pneumonia, and Listeria meningitis. In patients with ulcerative colitis, these included gastroenteritis, ophthalmic herpes zoster, pneumonia, and listeriosis.

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Billing codes (cont'd)

Selarsdi™ (ustekinumab-aekn)
Injection • 45mg/0.5mL • 90mg/mL

HCPCS level II code[2,6]

Code	Description
Q9998	Injection, ustekinumab-aekn (selarsdi), 1 mg

HCPCS = Healthcare Common Procedure Coding System

Important: When billing for drugs that have one HCPCS level II code but multiple routes of administration, the use of the JA and JB modifiers is generally required.

Modifier	Description
JA	Intravenous administration
JB	Subcutaneous administration

Use modifier JB (subcutaneous administration) when billing for the subcutaneous injection of the prefilled syringe.

HCPCS billing units[1,7]

Total dose	Packaging	Number of billing units[g]
45 mg	45 mg/0.5 mL single-dose prefilled syringe	45
90 mg	90 mg/mL single-dose prefilled syringe	90

[g]Each 1 mg dose of SELARSDI equals 1 billing unit.

CPT® code[3]

Code	Description
96372	Therapeutic, prophylactic, or diagnostic injection; subcutaneous injection or intramuscular

CPT® = Current Procedural Terminology

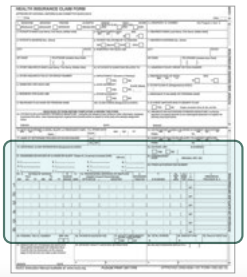
IMPORTANT SAFETY INFORMATION (cont'd)

Infections (cont'd)

Treatment with SELARSDI should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to initiating use of SELARSDI 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 while on treatment with SELARSDI and discontinue SELARSDI for serious or clinically significant infections until the infection resolves or is adequately treated.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Sample CMS-1500 claim form[2-4,6,7,12]



Healthcare providers who administer SELARSDI to patients should submit manual claims on the CMS-1500 claim form. The following is sample coding for submitting a manual claim for SELARSDI 45 mg/0.5 mL prefilled syringe for subcutaneous injection.

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.

21 — A. L40.0 | B. | C. | D. | E. | F. | G. | H. | I. | J. | K. | L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

24B | 24D | 24E | 24F | 24G

24A

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. QUAL.	J. RENDERING PROVIDER ID. #
1 N4 51759050532 ML0.5 MM DD YY		11		Q9998	JB JZ	A		45		NPI	
2 MM DD YY		11		96372		A		1		NPI	
3										NPI	

SUPPLIER INFO

See page 8 for descriptions of additional coding that may be required on claims.

Item 21	**Diagnosis or nature of illness or injury:** Enter the appropriate ICD-10-CM diagnosis code(s) on each line
Item 24A	**Date(s) of service:** Enter date(s) of service and provide applicable qualifiers in shaded line if required by the payer. If the NDC and NDC units are required by payer, enter in the shaded portion of line above dates of service
Item 24B	**Place of service:** Enter the appropriate place of service code
Item 24D	**Procedures, services, or supplies:** Enter the CPT® or HCPCS code(s) and modifier(s) as required by payers

Example:

Line 1: Q9998 – Injection, ustekinumab-aekn (selarsdi), 1 mg
JB – Modifier to indicate subcutaneous administration
JZ – Modifier to attest that there was no drug amount discarded

Line 2: 96372 – CPT® code for drug administration: subcutaneous injection or intramuscular

Item 24E	**Diagnosis pointer:** Enter the diagnosis code reference letter (A-L)
Item 24F	**Charges:** Enter the total charges for each service
Item 24G	**Days or units:** Enter the number of units related to the service or product

SELARSDI HCPCS units: 1 mg = 1 unit | 45 mg = 45 units | 90 mg = 90 units

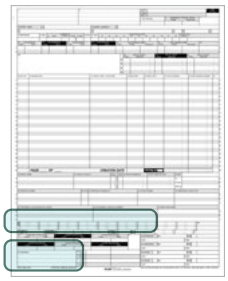
IMPORTANT SAFETY INFORMATION (cont'd)

Theoretical Risk for Vulnerability to Particular Infections

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria (including nontuberculous, environmental mycobacteria), Salmonella (including nontyphi strains), and Bacillus

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Sample CMS-1450 (UB-04) claim form[2,3,5-7,13,14]



Institutional healthcare providers who administer SELARSDI to patients should submit manual claims on the CMS-1450 (UB-04) claim form. The following is sample coding for submitting a manual claim for SELARSDI 45 mg/0.5 mL prefilled syringe for subcutaneous injection.

42	43	44	45	46	47
42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES
0636	SELARSDI	Q9998JB		45	
0940	Other therapeutic services	96372		1	

67	
66 DX	L40.50
69 ADMIT DX	70 PATIENT REASON DX

See page 8 for descriptions of additional coding that may be required on claims.

FL 42 **Revenue code:** List revenue codes in ascending order

FL 43 **Revenue description:** Enter narrative description for corresponding revenue code. If the NDC and NDC units are required by the payer, they should be entered here in the requested format (eg, N4 and ML qualifiers)

FL 44 **HCPCS codes:** Enter the CPT® or HCPCS code(s) and modifier(s) as required by payers

Example:
Line 1: Q9998 – Injection, ustekinumab-aekn (selarsdi), 1 mg
JB – Modifier to indicate subcutaneous administration

Line 2: 96372 – CPT® code for drug administration: subcutaneous injection or intramuscular

FL 46 **Service units:** Enter the number of units related to the service or product

SELARSDI HCPCS units: 1 mg = 1 unit | 45 mg = 45 units | 90 mg = 90 units

FL 47 **Charges:** Enter the total charges for each service

FL 67 **Diagnosis:** Enter the appropriate ICD-10-CM diagnosis code. Additional diagnoses should be included in form locator 67-A-Q

IMPORTANT SAFETY INFORMATION (cont'd)

Theoretical Risk for Vulnerability to Particular Infections (cont'd)

Calmette-Guerin (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients. It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with ustekinumab products may be susceptible to these types of infections. Consider diagnostic testing, eg, tissue culture, stool culture, as dictated by clinical circumstances.

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Coverage considerations

Factors that may influence coverage

Commercial insurers, Medicare, and Medicaid will generally cover parenteral drugs for their approved US Food and Drug Administration (FDA) indications and any associated professional administration services. However, coverage may vary depending on the payer or individual health plan.

Medical necessity

Payers may require evidence supporting the medical necessity of a therapy. This evidence may include:

- Patient's medical condition and history
- A physician's statement or Letter of Medical Necessity
- Supporting literature (eg, peer-reviewed studies and compendia monographs)
- Full Prescribing Information
- Availability of alternative treatments

Administrative considerations

Administrative considerations for payers may include:

- Site of care specifications in a coverage policy
- In-network or participating provider
- Referral or prior authorization

Prior authorization

Prior authorization (PA) is a process required by many health plans to verify the medical necessity and appropriate use of certain treatments or services. Providers must submit evidence to support the PA request. While not used in Original Medicare, PA is common in Medicare Advantage and commercial insurance plans. If patients do not meet the criteria for a needed drug, they can request an exception or coverage determination.

Exception request

An exception request is a type of coverage determination that asks a payer to reconsider a coverage denial. The prescriber is required to submit evidence of medical necessity. It may be helpful to respond to the stated reason(s) coverage was denied (eg, drug not on formulary, dose restrictions, step therapy).
If the request is not granted, the payer will provide a written explanation and include information about how to request an appeal.

Appeals

If an appeal needs to be filed, contact the payer for guidance as individual policies may vary.

IMPORTANT SAFETY INFORMATION (cont'd)

Pre-Treatment Evaluation of Tuberculosis (TB)
Evaluate patients for TB prior to initiating treatment with SELARSDI. Do not administer SELARSDI to patients with active TB infection. Initiate treatment of latent TB before administering SELARSDI. Consider anti-tuberculosis therapy prior to initiation of SELARSDI in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients receiving SELARSDI for signs and symptoms of active TB during and after treatment.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

Teva Shared Solutions for Biosimilars provides a seamless support experience for you and your patients

Selarsdi™ (ustekinumab-aekn)
Injection • 45mg/0.5mL • 90mg/mL

teva | Shared Solutions for Biosimilars

Teva Shared Solutions offers a range of services

- Understanding insurance benefits
- Financial assistance
- Injection education

To enroll patients or for reimbursement questions, call 1-888-587-3263
Learn more at SELARSDIhcp.com/savings-and-support

Teva is committed to helping make SELARSDI affordable and accessible

SELARSDI Savings Program

The SELARSDI Savings Program may help eligible, commercially insured patients pay as little as **$0 per month**.

Enroll at SELARSDIcopay.com

SELARSDI ABBREVIATED TERMS AND CONDITIONS

The SELARSDI Savings Program is available to eligible patients who have been prescribed SELARSDI and have commercial prescription insurance. This program is intended for the benefit of patients, not their insurance plans or other third parties. Maximum program assistance per prescription and annual benefit limits per individual apply and out-of-pocket expenses may vary. Patient is responsible for costs above maximum benefit amounts. This program is restricted to residents of the United States and United States territories. Uninsured and cash-paying patients are NOT eligible for this program. Patients enrolled in any state or federally funded healthcare program, including but not limited to, Medicare, Medigap, Medicaid, VA, DOD, TRICARE, Puerto Rico Government Health Insurance Plan, Medicare-eligible patients enrolled in an employer-sponsored health plan or prescription drug benefit program for retirees, are NOT eligible for this program. Teva Pharmaceuticals, Inc. and its affiliates reserve the right to change, rescind, revoke, or discontinue this program at any time without notice. Please see complete Terms and Conditions at SELARSDITandC.com.

IMPORTANT SAFETY INFORMATION (cont'd)

Malignancies

Ustekinumab products are immunosuppressants and may increase the risk of malignancy. Malignancies were reported among patients who received ustekinumab in clinical trials. The safety of ustekinumab products has not been evaluated in patients who have a history of malignancy or who have a known malignancy. There have been post-marketing reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving ustekinumab products who had pre-existing risk factors for developing non-melanoma skin cancer (NMSC). All patients receiving SELARSDI, especially those greater than 60 years of age or those with a history of Psoralen plus ultraviolet A (PUVA) or prolonged immunosuppressant treatment, should be monitored for the appearance of NMSC.

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IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with ustekinumab products. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue SELARSDI.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

References: 1. SELARSDI™ (ustekinumab-aekn) injection [current prescribing information]. Alvotech USA Inc. Leesburg, VA. **2.** Centers for Medicare & Medicaid Services. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) application summaries and coding recommendation: third quarter, 2024 HCPCS coding cycle. Accessed December 19, 2024. https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-3-2024-drugs-and-biologicals.pdf. **3.** Find-A-Code. ICD-10-CM. Accessed December 19, 2024. https://www.findacode.com/search/search.php. **4.** Centers for Medicare & Medicaid Services. Pub 100-04: Medicare claims processing. Accessed December 19, 2024. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r1401cp.pdf. **5.** Blue Cross Blue Shield of Illinois. National Drug Code (NDC) FAQs. Accessed January 30, 2025. https://www.bcbsil.com/pdf/pharmacy/ndc_faqs.pdf. **6.** Noridian Medicare. Modifiers. Accessed December 19, 2024. https://med.noridianmedicare.com/web/jeb/topics/modifiers. **7.** Novitas. Appropriate drug billing Part B. Accessed January 30, 2025. https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00156731. **8.** Centers for Medicare & Medicaid Services. MLN Matters. Billing requirements for OPPS providers with multiple service locations. Accessed December 19, 2024. https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se18002.pdf. **9.** Centers for Medicare & Medicaid Services. JW and JZ modifier policy FAQs. January 2025. Accessed January 30, 2024. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf. **10.** Centers for Medicare & Medicaid Services. Place of service code set. Accessed December 19, 2024. https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets. **11.** Noridian Medicare. Revenue codes. Accessed December 19, 2024. https://med.noridianmedicare.com/ web/jea/topics/claim-submission/revenue-codes. **12.** Centers for Medicare & Medicaid Services. Medicare claims processing manual chapter 26 - Completing and processing form CMS-1500 data set. Accessed January 30, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf. **13.** Centers for Medicare & Medicaid Services. Medicare claims processing manual chapter 25 - completing and processing the form CMS-1450 data set. Accessed December 19, 2024. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf. **14.** Centers for Medicare & Medicaid Services. Medicare claims processing manual chapter 25 revision. Accessed January 30, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/ Transmittals/downloads/R1973CP.pdf.

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