Fasenra® (benralizumab) Subcutaneous Injection 30 mg | AstraZeneca Access 360™

Access and Reimbursement Guide

The AstraZeneca Access 360™ program provides personal support to connect patients to affordability programs and streamline access and reimbursement for FASENRA.

For more information, call AstraZeneca Access 360™ at **1-833-360-4357**, Monday through Friday, 8 AM to 8 PM ET.

1-833-360-HELP
(1-833-360-4357)

1-833-FAX-A360
(1-833-329-2360)

www.MyAccess360.com

Access360@AstraZeneca.com

INDICATION

FASENRA is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

- FASENRA is not indicated for treatment of other eosinophilic conditions
- FASENRA is not indicated for the relief of acute bronchospasm or status asthmaticus

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Known hypersensitivity to benralizumab or excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (eg, anaphylaxis, angioedema, urticaria, rash) have occurred after administration of FASENRA. These reactions generally occur within hours of administration, but in some instances have a delayed onset (ie, days). Discontinue in the event of a hypersensitivity reaction.

Please see additional Important Safety Information throughout this guide and accompanying full Prescribing Information including Patient Information.

Prior Authorization and Appeal Checklists

These checklists are intended to simplify the prior authorization (PA) and denial/appeal process for FASENRA® (benralizumab).*

PRIOR AUTHORIZATION (PA) CHECKLIST

The items below may be necessary to obtain a PA decision from a health plan. Please ensure you have all information below prior to submitting the PA.

☐ **Completed PA request form (some health plans require specific forms)** including the following:

- ☐ Patient name, insurance policy number, and date of birth
- ☐ Physician name and NPI number
- ☐ Facility name and NPI number
- ☐ Date of service
- ☐ Patient diagnosis (ICD-10 code[s])
- ☐ Relevant procedure and HCPCS codes for services/products to be performed/provided
- ☐ Product NDC
- ☐ Setting of care

☐ **Letter of medical necessity and relevant clinical support**

- ☐ Include the Provider ID number in the letter

☐ **Documentation that supports the treatment decision, such as:**

- ☐ Previous given treatments/therapies
- ☐ Patient-specific clinical notes detailing the relevant diagnosis
- ☐ Relevant laboratory results
- ☐ Product Prescribing Information

Prior authorization requirements vary by health plan and may require pre-approval. Please contact the patient's health plan for specific PA requirements to ensure efficient and timely review. Failure to obtain prior authorization can result in non-payment by the plan.

Prior to submission, please keep track of dates and methods of correspondence (phone, email, and written); record the names of insurance contacts and reviewers with whom you speak; and summarize conversations and written documents issued by the insurer.

DENIAL AND APPEAL CHECKLIST

If the health plan denied a PA for an AstraZeneca medicine:

☐ **Review the denial notification** to understand the reason and circumstances that need to be addressed and explained in the appeal letter.

☐ **Understand the plan's most recent explanation of benefits** or contact a representative at the insurer to verify where the appeal should be sent and any deadlines.

☐ **Write an appeal letter.** If you need additional information regarding this process, please contact Access 360 for examples.

If you or your patient have not received a decision within 30 days:

☐ **Follow up with the health plan.** Confirm that the appeal letter was received and ask about its status. If the coverage denial was upheld, you could resubmit another appeal with new information or ask for a Supervisor or Manager to assist.

If the denial is upheld again:

☐ **Ask for a one-time exception or consider filing a complaint** with the state's insurance commissioner.

☐ **If the insurer continues to deny the claim:** Your patient may request an external appeal (the process varies by state law), in which an independent third party will review the claim and make a final, binding decision.

☐ Please contact your Field Reimbursement Manager (FRM) or Access 360 if you need additional support.

***Providers and patients are encouraged to contact the patient's insurer for detailed instructions on completing a PA or how to appeal/overturn a denial. If you have any questions, or need guidance, please contact AstraZeneca Access 360™ or your Field Reimbursement Manager at 1-833-360-HELP (1-833-360-4357).**

IMPORTANT SAFETY INFORMATION (cont'd)

Acute Asthma Symptoms or Deteriorating Disease

FASENRA should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

Please see additional Important Safety Information throughout this guide and accompanying full Prescribing Information including Patient Information.

Coding

It is important to note that the codes identified below are examples only. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of the following codes does not guarantee reimbursement.

National Drug Code (NDC)

10-digit NDC

Administration Method	Dosage	Code
Physician-Administered	FASENRA® 30 mg/mL single-dose prefilled syringe	0310-1730-30
Self-Administered	FASENRA Pen™ 30 mg/mL single-dose autoinjector	0310-1830-30

11-digit NDC

Administration Method	Dosage	Code
Physician-Administered	FASENRA® 30 mg/mL single-dose prefilled syringe	00310-1730-30
Self-Administered	FASENRA Pen™ 30 mg/mL single-dose autoinjector	00310-1830-30

Current Procedural Terminology® (CPT)[1]

	Code	Description
Injection Administration	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
	96401	Chemotherapy administration, subcutaneous or intramuscular; nonhormonal antineoplastic
Injection Education	99211	Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified healthcare professional

Healthcare Common Procedure Coding System (HCPCS)[2]

Code	Description	Package Size	Billing Units
J0517	Injection, benralizumab, 1 mg	30 mg/mL single-dose prefilled syringe/autoinjector	30

Diagnosis Codes[3]

ICD-10-CM	Description
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation

Home Healthcare Setting Codes[1,2]

HCPCS

Code	Description
G0495	Skilled services of a registered nurse (RN), in the training and/or education of a patient or family member, in the home health or hospice setting, each 15 minutes
G0496	Skilled services of a licensed practical nurse (LPN), in the training and/or education of a patient or family member, in the home health or hospice setting, each 15 minutes

CPT

Code	Description
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (List separately in addition to code for primary procedure)

IMPORTANT SAFETY INFORMATION (cont'd)

Reduction of Corticosteroid Dosage

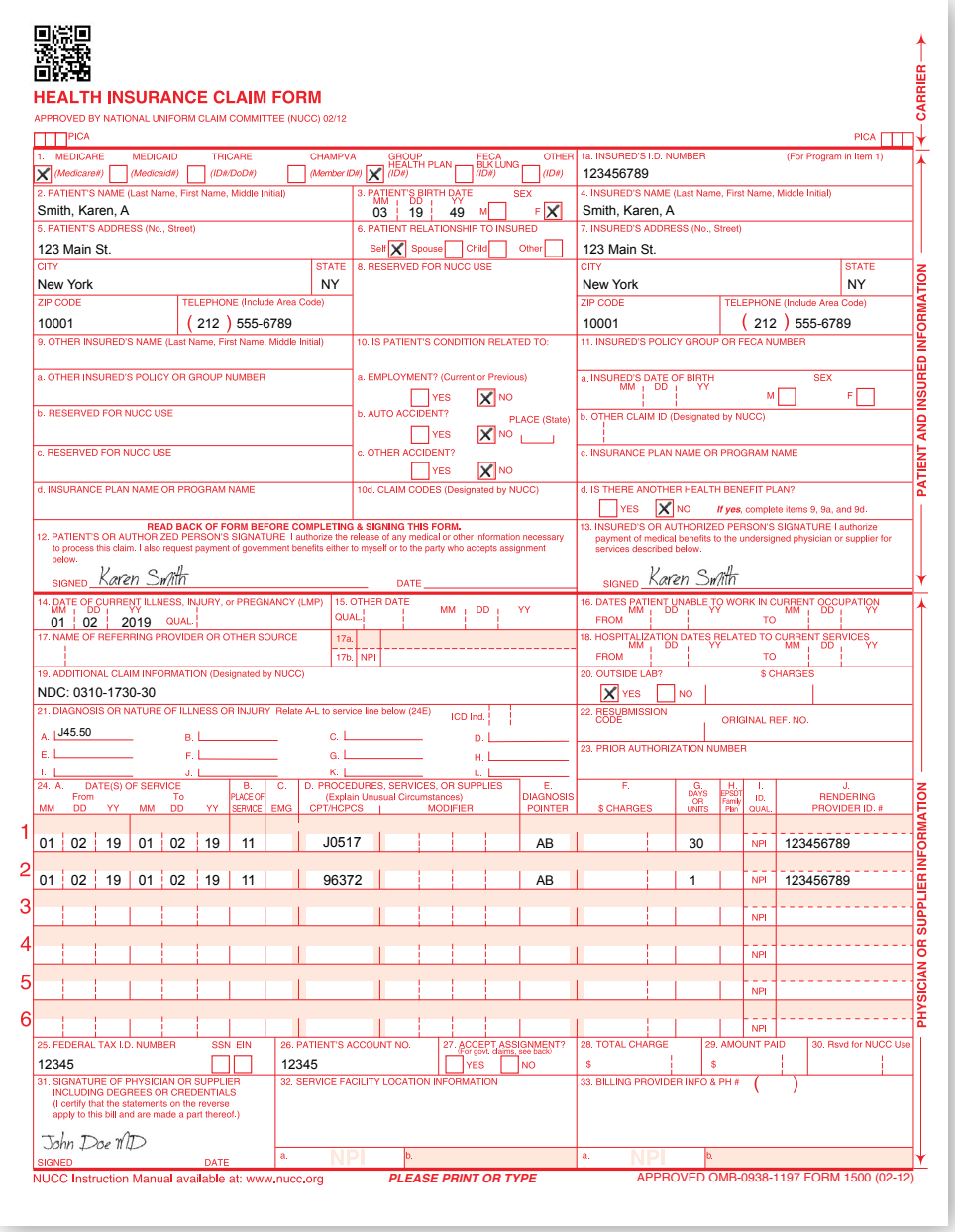
Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with FASENRA. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection

It is unknown if FASENRA will influence a patient's response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with FASENRA. If patients become infected while receiving FASENRA and do not respond to anti-helminth treatment, discontinue FASENRA until infection resolves.

CMS–1500 Annotated Claim Form

Prescribers use this form when billing insurers for medication administered in the physician's office and for their professional services.



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#)
X				X		

1a. INSURED'S I.D. NUMBER (For Program in Item 1)	PICA
123456789	

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)	3. PATIENT'S BIRTH DATE MM DD YY	SEX	4. INSURED'S NAME (Last Name, First Name, Middle Initial)
Smith, Karen, A	03 19 49	M / F X	Smith, Karen, A

5. PATIENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP TO INSURED	7. INSURED'S ADDRESS (No., Street)
123 Main St.	Self X Spouse Child Other	123 Main St.

CITY	STATE	8. RESERVED FOR NUCC USE	CITY	STATE
New York	NY		New York	NY

ZIP CODE	TELEPHONE (Include Area Code)	ZIP CODE	TELEPHONE (Include Area Code)
10001	(212) 555-6789	10001	(212) 555-6789

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 X	a. INSURED'S DATE OF BIRTH MM DD YY SEX M / F
b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? YES / NO X PLACE (State)	b. OTHER CLAIM ID (Designated by NUCC)
c. RESERVED FOR NUCC USE	c. OTHER ACCIDENT? YES / NO X	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 X *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 Karen Smith 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 Karen Smith

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY	QUAL.	15. OTHER DATE MM DD YY	QUAL.	16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY
01 02 2019				

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	17a.	18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY
	17b. NPI	

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)	20. OUTSIDE LAB?	$ CHARGES
NDC: 0310-1730-30	YES X / NO	

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.				22. RESUBMISSION CODE	ORIGINAL REF. NO.
A. J45.50	B.	C.	D.		
E.	F.	G.	H.	23. PRIOR AUTHORIZATION NUMBER	
I.	J.	K.	L.		

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 01 02 19 01 02 19	11		J0517		AB		30		NPI	123456789
2 01 02 19 01 02 19	11		96372		AB		1		NPI	123456789
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)	28. TOTAL CHARGE	29. AMOUNT PAID	30. Rsvd for NUCC Use
12345	12345	YES / NO	$	$	

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.)	32. SERVICE FACILITY LOCATION INFORMATION	33. BILLING PROVIDER INFO & PH # ( )
John Doe MD	a. NPI b.	a. NPI b.
SIGNED DATE		

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

The suggestions contained on this form are for example only and AstraZeneca makes no representation that the information is accurate or that it will comply with the requirements of any particular payer/insurer. Providers are solely responsible for determining the billing and coding requirements applicable to any payer/insurer. The information provided here is not intended to be conclusive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor. AstraZeneca makes no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use. The use of this information does not guarantee payment or that any payment received will cover your costs.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

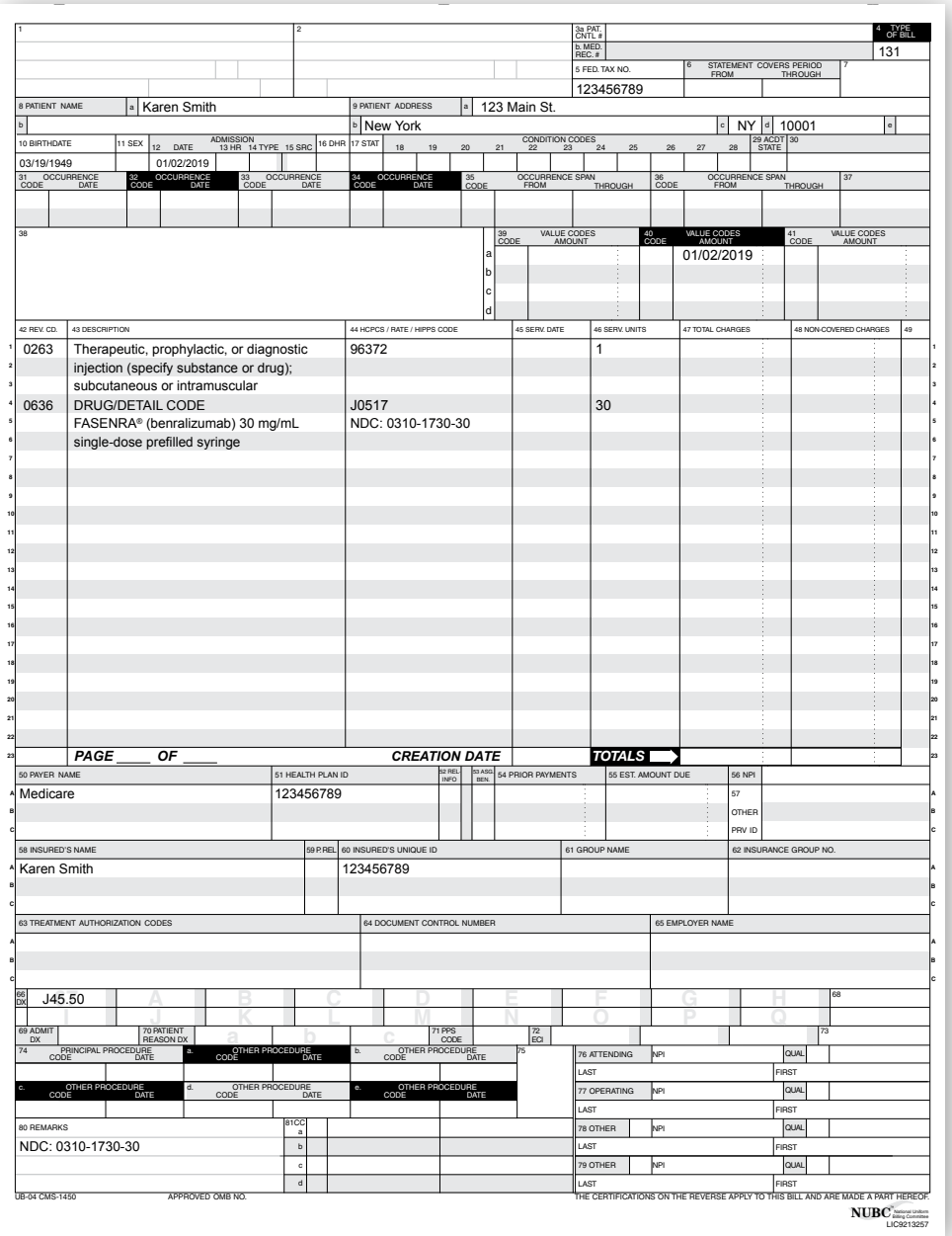
The most common adverse reactions (incidence ≥ 5%) include headache and pharyngitis.

Injection site reactions (eg, pain, erythema, pruritus, papule) occurred at a rate of 2.2% in patients treated with FASENRA compared with 1.9% in patients treated with placebo.

Please see additional Important Safety Information throughout this guide and accompanying full Prescribing Information including Patient Information.

UB–04 Annotated Claim Form

Hospitals use this form when billing insurers for medication administered in the inpatient or outpatient setting. Outpatient hospitals should bill with the appropriate revenue code.



1		2		3a PAT. CNTL. #		4 TYPE OF BILL	
				b. MED. REC. #			131
				5 FED. TAX NO.	123456789	6 STATEMENT COVERS PERIOD FROM	THROUGH
8 PATIENT NAME	a Karen Smith	9 PATIENT ADDRESS	a 123 Main St.				
b		b New York	c NY	d 10001	e		
10 BIRTHDATE	11 SEX	12 ADMISSION DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT
03/19/1949		01/02/2019					

31 OCCURRENCE CODE	DATE	32 OCCURRENCE CODE	DATE	33 OCCURRENCE CODE	DATE	34 OCCURRENCE CODE	DATE	35 OCCURRENCE SPAN CODE	FROM	THROUGH	36 OCCURRENCE SPAN CODE	FROM	THROUGH	37

38		39 VALUE CODES CODE	AMOUNT	40 VALUE CODES CODE	AMOUNT	41 VALUE CODES CODE	AMOUNT
	a				01/02/2019		
	b						
	c						
	d						

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1	0263	Therapeutic, prophylactic, or diagnostic	96372		1			
2		injection (specify substance or drug);						
3		subcutaneous or intramuscular						
4	0636	DRUG/DETAIL CODE	J0517		30			
5		FASENRA® (benralizumab) 30 mg/mL	NDC: 0310-1730-30					
6		single-dose prefilled syringe						
7–22								
23		PAGE ____ OF ____ CREATION DATE			TOTALS			

	50 PAYER NAME	51 HEALTH PLAN ID	52 REL INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	
A	Medicare	123456789					57 OTHER PRV ID	A
B								B
C								C

	58 INSURED'S NAME	59 P REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
A	Karen Smith		123456789		
B					
C					

	63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME
A			
B			
C			

66 DX	J45.50	A	B	C	D	E	F	G	H	68
		I	J	K	L	M	N	O	P	Q	

69 ADMIT DX	70 PATIENT REASON DX	a	b	c	71 PPS CODE	72 ECI	73

74 PRINCIPAL PROCEDURE CODE	DATE	a. OTHER PROCEDURE CODE	DATE	b. OTHER PROCEDURE CODE	DATE	75
c. OTHER PROCEDURE CODE	DATE	d. OTHER PROCEDURE CODE	DATE	e. OTHER PROCEDURE CODE	DATE	

80 REMARKS	81CC		76 ATTENDING	NPI	QUAL	
NDC: 0310-1730-30	a		LAST		FIRST	
	b		77 OPERATING	NPI	QUAL	
	c		LAST		FIRST	
	d		78 OTHER	NPI	QUAL	
			LAST		FIRST	
			79 OTHER	NPI	QUAL	
			LAST		FIRST	

UB-04 CMS-1450 APPROVED OMB NO. THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

NUBC National Uniform Billing Committee

LIC9213257

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Understanding Medicare

How prescription coverage works under Medicare

Medicare is a federal health insurance program that mainly provides coverage for people who are over the age of 65, blind, or disabled. This program pays for medical services and procedures that have been determined as "reasonable and necessary." It is important to note that there are various parts of Medicare, and benefits vary based on the type of coverage you select.

Medicare Part A

Hospital Insurance:

Covers inpatient hospital services and certain follow-up care.

Medicare Part B

Medical Insurance:

Covers medically necessary services and supplies. Also covers drugs prescribed and administered by a healthcare provider.

Medicare Part C

Medicare Advantage:

Also known as Medicare Advantage, covers Part A and Part B benefits and could also include prescription coverage.

Medicare Part D

Medicare Prescription Drug Coverage:

These are private insurance plans specifically for prescription drug coverage.

Which prescription drugs are covered under Medicare Part B?

In general, Medicare Part B covers drugs that are not self-administered. This includes drugs given by healthcare providers in their offices and drugs infused in outpatient settings. The yearly Part B deductible usually covers these drugs.

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USE IN SPECIFIC POPULATIONS

A pregnancy exposure registry monitors pregnancy outcomes in women exposed to FASENRA during pregnancy. To enroll call 1-877-311-8972 or visit www.mothertobaby.org/fasenra.

The data on pregnancy exposure from the clinical trials are insufficient to inform on drug-associated risk. Monoclonal antibodies such as benralizumab are transported across the placenta during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy.

Please read full Prescribing Information, including Patient Information.

You are encouraged to report negative side effects of AstraZeneca prescription drugs by calling 1-800-236-9933. If you prefer to report these to the FDA, either visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

Fasenra® (benralizumab) Subcutaneous Injection 30 mg

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References: 1. American Medical Association. *CPT® 2019 Professional Edition.* Chicago, IL: American Medical Association; 2019. **2.** Centers for Medicare & Medicaid Services. HCPCS Release & Code Sets. Alpha-Numeric HCPCS File. July 31, 2019. **3.** American Medical Association. *ICD-10-CM 2019: The Complete Official Codebook.* Chicago, IL: American Medical Association; 2019.

AstraZeneca