

**Texas Prior Authorization Program
Clinical Criteria**

Monoclonal Antibodies (Fasenra and Nucala)

This criteria was recommended for review by the Vendor Drug Program to ensure appropriate and safe utilization

Clinical Information Included in this Document

Fasenra (Benralizumab)

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Nucala (Mepolizumab)

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Revision Notes

Added GCN for Nucala (52416) to the Drugs Requiring PA table and to the Duplicate Monoclonal Antibody Therapy table

Updated Nucala criteria:

- Added diagnosis of chronic rhinosinusitis with nasal polyps for clients \geq 18 years of age that had an inadequate response to intranasal corticosteroids



Fasenra (Benralizumab)

Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
FASENRA PEN 30 MG/ML	47019

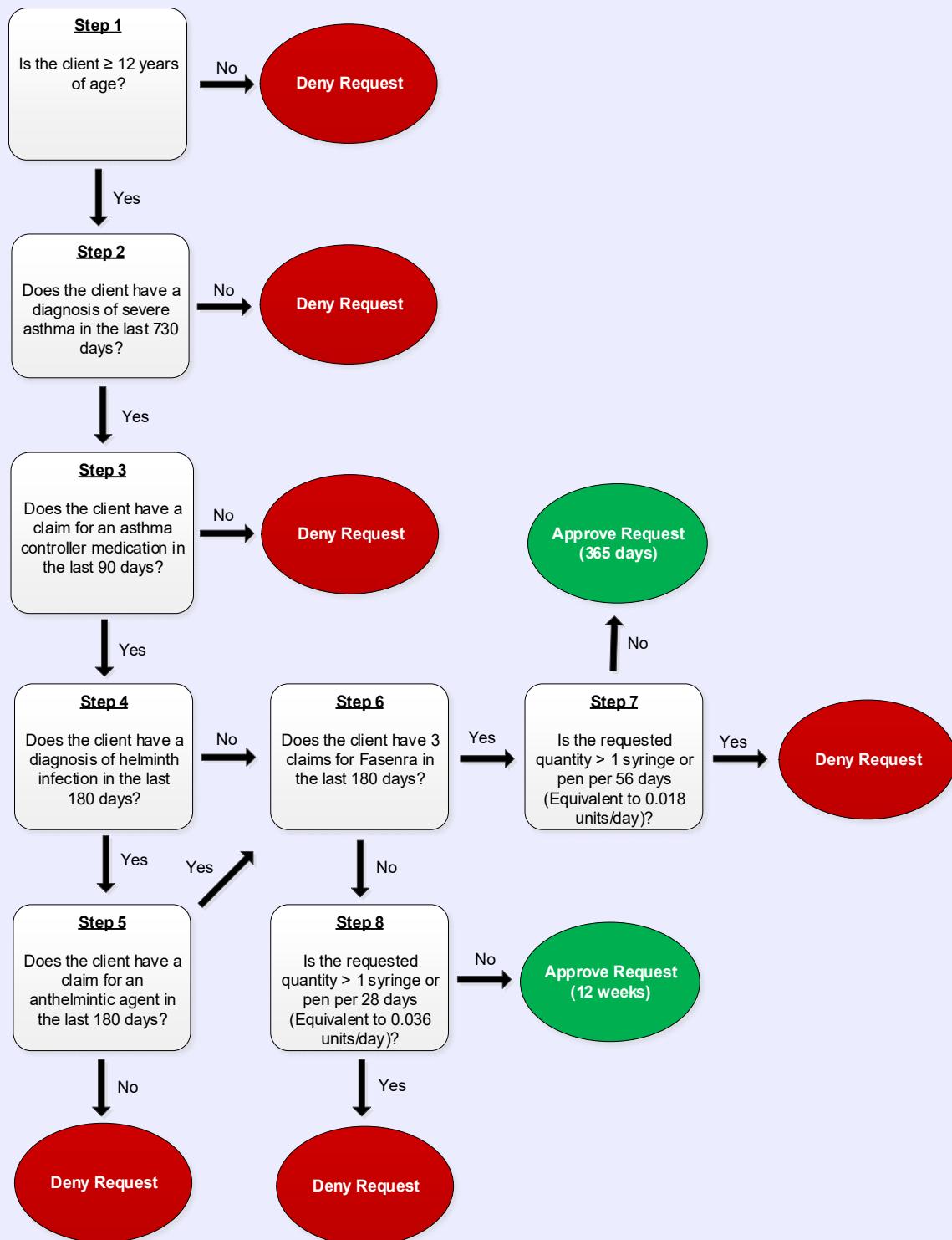
**Fasenra (Benralizumab)****Clinical Criteria Logic**

1. Is the client greater than or equal to (\geq) 12 years of age?
[] Yes (Go to #2)
[] No (Deny)
2. Does the client have a **diagnosis of severe asthma** in the last 730 days?
[] Yes (Go to #3)
[] No (Deny)
3. Does the client have a claim for an **asthma controller medication** in the last 90 days?
[] Yes (Go to #4)
[] No (Deny)
4. Does the client have a **diagnosis of helminth infection** in the last 180 days?
[] Yes (Go to #5)
[] No (Go to #6)
5. Does the client have a claim for an **anthelmintic agent** in the last 180 days?
[] Yes (Go to #6)
[] No (Deny)
6. Does the client have 3 claims for Fasenra (benralizumab) in the last 180 days?
[] Yes (Go to #7)
[] No (Go to #8)
7. Is the requested quantity greater than ($>$) 1 syringe or pen per 56 days (Equivalent to 0.018 units/day)?
[] Yes (Deny)
[] No (Approve – 365 days)
8. Is the requested quantity greater than ($>$) 1 syringe or pen per 28 days (Equivalent to 0.036 units/day)?
[] Yes (Deny)
[] No (Approve – 12 weeks)



Fasenra (Benralizumab)

Clinical Criteria Logic Diagram



**Nucala (Mepolizumab)****Drugs Requiring Prior Authorization**

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
NUCALA 100 MG/ML AUTO-INJECTOR	46414
NUCALA 100 MG/ML SYRINGE	46413
NUCALA 40 MG/0.4 ML SYRINGE	52416



Nucala (Mepolizumab)

Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 12 years of age?
[] Yes (Go to #2)
[] No (Deny)
2. Does the client have a **diagnosis of severe asthma** in the last 730 days?
[] Yes (Go to #3)
[] No (Go to #4)
3. Does the client have a claim for an **asthma controller medication** in the last 90 days?
[] Yes (Go to #11)
[] No (Deny)
4. Does the client have a diagnosis of **hypereosinophilic syndrome (HES)** in the last 730 days?
[] Yes (Go to #8)
[] No (Go to #5)
5. Does the client have a diagnosis of **eosinophilic granulomatosis with polyangiitis (EGPA)** in the last 730 days?
[] Yes (Go to #7)
[] No (Go to #6)
6. Does the client have a diagnosis of **chronic rhinosinusitis with nasal polyps (CRSwNP)** in the last 730 days?
[] Yes (Go to #7)
[] No (Deny)
7. Is the client greater than or equal to (\geq) 18 years of age?
[] Yes, and the client has a diagnosis of EGPA (Go to #8)
[] Yes, and the client has a diagnosis of CRSwNP (Go to #10)
[] No (Deny)
8. Has the client had a trial of **oral glucocorticoid therapy** in the last 45 days, or is oral glucocorticoid therapy contraindicated?
[] Yes (Go to #9)
[] No (Deny)

9. Has the client had a **trial of cyclophosphamide, azathioprine, methotrexate or leflunomide** in the last 90 days, or is a trial of these medications contraindicated?

Yes (Go to #11)
 No (Deny)

10. Will the client have concurrent therapy with **intranasal corticosteroids**?

Yes (Go to #11)
 No (Deny)

11. Does the client have a **diagnosis of helminth infection** in the last 180 days?

Yes (Go to #12)
 No (Go to #13)

12. Does the client have a claim for an **anthelmintic agent** in the last 180 days?

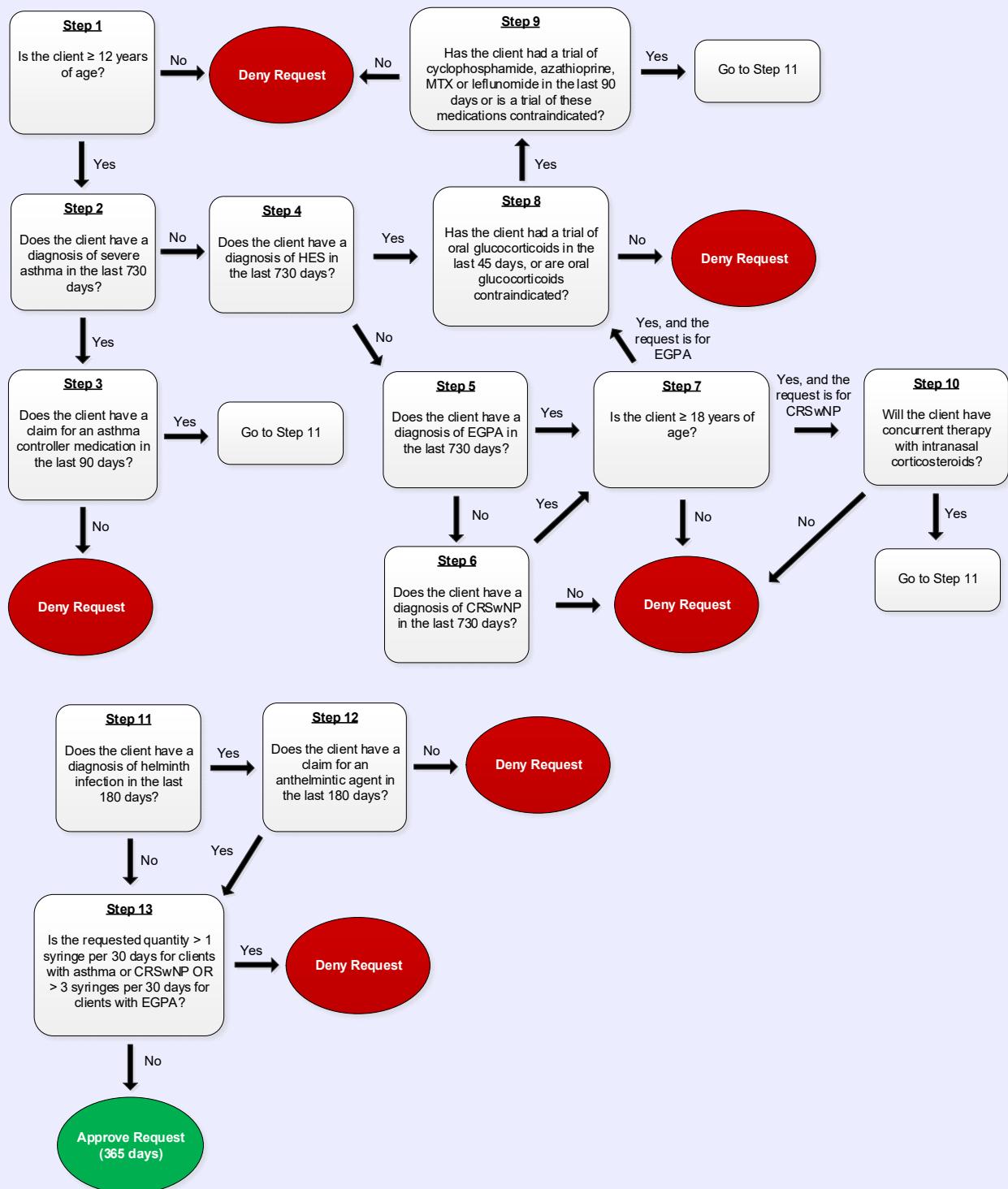
Yes (Go to #13)
 No (Deny)

13. Is the requested quantity greater than (>) 1 syringe per 30 days for clients with asthma or CRSwNP OR greater than (>) 3 syringes per 30 days for clients with EGPA or HES?

Yes (Deny)
 No (Approve – 365 days)



Nucala (Mepolizumab)





Monoclonal Antibodies for Asthma

Clinical Criteria Supporting Tables

Diagnosis of severe asthma Required quantity: 1 Look back timeframe: 730 days	
ICD-10 Code	Description
J4550	SEVERE PERSISTENT ASTHMA, UNCOMPLICATED
J4551	SEVERE PERSISTENT ASTHMA, WITH (ACUTE) EXACERBATION
J4552	SEVERE PERSISTENT ASTHMA, WITH STATUS ASTHMATICUS

History of an asthma controller medication Number of claims: 1 Look back timeframe: 90 days	
Label Name	GCN
ADVAIR 100-50 DISKUS	50584
ADVAIR 250-50 DISKUS	50594
ADVAIR 500-50 DISKUS	50604
ADVAIR HFA 115-21MCG INHALER	97136
ADVAIR HFA 230-21MCG INHALER	97137
ADVAIR HFA 45-21MCG INHALER	97135
ALVESCO 160 MCG INHALER	24152
ALVESCO 80 MCG INHALER	24149
ARNUITY ELLIPTA 100 MCG INH	37007
ARNUITY ELLIPTA 200 MCG INH	37008
ARNUITY ELLIPTA 50 MCG INH	44783
ASMANEX HFA 100 MCG INHALER	37566
ASMANEX HFA 200 MCG INHALER	37565
ASMANEX TWISTHALER 110 MCG #30	99721
ASMANEX TWISTHALER 220 MCG #30	24928
ASMANEX TWISTHALER 220 MCG #60	24929
ASMANEX TWISTHALR 220 MCG #120	18987
BREO ELLIPTA 100-25MCG INH	34647
BREO ELLIPTA 200-25MCG INHALER	35808
BUDESONIDE 0.25MG/2ML INHALATION SUSPENSION	17957
BUDESONIDE 0.5MG/2ML INHALATION SUSPENSION	17958

History of an asthma controller medication	
Number of claims: 1	
Look back timeframe: 90 days	
Label Name	GCN
BUDESONIDE 1MG/2ML INHALATION SUSPENSION	62980
DULERA 100 MCG/5 MCG INHALER	28766
DULERA 200 MCG/5 MCG INHALER	28767
FLOVENT 100MCG DISKUS	53633
FLOVENT 250MCG DISKUS	53634
FLOVENT 50MCG DISKUS	53635
FLOVENT HFA 110 MCG INHALER	53636
FLOVENT HFA 220 MCG INHALER	53639
FLOVENT HFA 44 MCG INHALER	53638
FLUTICASONE-SALMETEROL 55-14	42956
FLUTICASONE-SALMETEROL 113-14	42957
FLUTICASONE-SALMETEROL 232-14	42958
FLUTICASONE-SALMETEROL 100-50	50584
FLUTICASONE-SALMETEROL 250-50	50594
FLUTICASONE-SALMETEROL 500-50	50604
HYDROCORTISONE 20MG TABLET	26782
HYDROCORTISONE 5MG TABLET	26783
HYDROCORTONE 10MG TABLET	26781
MEDROL 16MG TABLET	27051
MEDROL 32MG TABLET	27055
MEDROL 4MG TABLET	27056
MEDROL 8MG TABLET	27058
METHYLPREDNISOLONE 16MG TABLET	27051
METHYLPREDNISOLONE 32MG TABLET	27055
METHYLPREDNISOLONE 4MG TABLET	27056
METHYLPREDNISOLONE 8MG TABLET	27058
MILLIPRED 5MG TABLET	26963
PREDNISOLONE 10MG/5ML SOLN	99610
PREDNISOLONE 15MG/5ML SOLN	26800
PREDNISOLONE 15MG/5ML SOLN	33806
PREDNISOLONE 20MG/5ML SOLN	14565
PREDNISOLONE 5MG/5ML SOLUTION	09115
PREDNISOLONE ODT 10MG TABLET	27108
PREDNISOLONE ODT 15MG TABLET	27109
PREDNISOLONE ODT 30MG TABLET	27114
PREDNISONE 10MG TABLET	27172

History of an asthma controller medication	
Number of claims: 1	
Look back timeframe: 90 days	
Label Name	GCN
PREDNISONE 1MG TABLET	27171
PREDNISONE 2.5MG TABLET	27173
PREDNISONE 20MG TABLET	27174
PREDNISONE 5 MG TABLET	27176
PREDNISONE 50MG TABLET	27177
PREDNISONE 5MG/5ML SOLUTION	27160
PREDNISONE 5MG/5ML SOLUTION	27161
PULMICORT 0.25 MG/2 ML RESPULE	17957
PULMICORT 0.5MG/2ML RESPULE	17958
PULMICORT 1 MG/2 ML RESPULE	62980
PULMICORT 180 MCG FLEXHALER	98025
PULMICORT 90 MCG FLEXHALER	98024
QVAR REDIHALER 40 MCG	43724
QVAR REDIHALER 80 MCG	43725
SYMBICORT 160-4.5 MCG INHALER	98500
SYMBICORT 80-4.5 MCG INHALER	98499
WIXELA 100-50 INHUB	50584
WIXELA 250-50 INHUB	50594
WIXELA 500-50 INHUB	50604

Diagnosis of hypereosinophilic syndrome	
Required diagnoses: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
D72110	IDIOPATHIC HYPEREOSINOPHILIC SYNDROME (IHES)
D72111	LYMPHOCYTIC VARIANT HYPEREOSINOPHILIC SYNDROME (LHES)
D72118	OTHER HYPEREOSINOPHILIC SYNDROME
D72119	HYPEREOSINOPHILIC SYNDROME (HES), UNSPECIFIED

Diagnosis of eosinophilic granulomatosis with polyangiitis	
Required diagnoses: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
M301	POLYARTERITIS WITH LUNG INVOLVEMENT [CHURG-STRAUSS]

Diagnosis of chronic rhinosinusitis with nasal polyps
Required diagnosis: 1
Look back timeframe: 730 days

ICD-10 Code	Description
J330	POLYP OF NASAL CAVITY
J331	POLYPOID SINUS DEGENERATION
J338	OTHER POLYP OF SINUS
J339	NASAL POLYP, UNSPECIFIED

History of an oral glucocorticoid
Number of claims: 1
Look back timeframe: 45 days

Label Name	GCN
HYDROCORTISONE 20MG TABLET	26782
HYDROCORTISONE 5MG TABLET	26783
HYDROCORTONE 10MG TABLET	26781
MEDROL 16MG TABLET	27051
MEDROL 32MG TABLET	27055
MEDROL 4MG TABLET	27056
MEDROL 8MG TABLET	27058
METHYLPREDNISOLONE 16MG TABLET	27051
METHYLPREDNISOLONE 32MG TABLET	27055
METHYLPREDNISOLONE 4MG TABLET	27056
METHYLPREDNISOLONE 8MG TABLET	27058
MILLIPRED 5MG TABLET	26963
PREDNISOLONE 10MG/5ML SOLN	99610
PREDNISOLONE 15MG/5ML SOLN	26800
PREDNISOLONE 15MG/5ML SOLN	33806
PREDNISOLONE 20MG/5ML SOLN	14565
PREDNISOLONE 5MG/5ML SOLUTION	09115
PREDNISOLONE ODT 10MG TABLET	27108
PREDNISOLONE ODT 15MG TABLET	27109
PREDNISOLONE ODT 30MG TABLET	27114
PREDNISONE 10MG TABLET	27172
PREDNISONE 1MG TABLET	27171
PREDNISONE 2.5MG TABLET	27173
PREDNISONE 20MG TABLET	27174
PREDNISONE 5 MG TABLET	27176

History of an oral glucocorticoid Number of claims: 1 Look back timeframe: 45 days	
Label Name	GCN
PREDNISONE 50MG TABLET	27177
PREDNISONE 5MG/5ML SOLUTION	27160
PREDNISONE 5MG/5ML SOLUTION	27161

History of cyclophosphamide, azathioprine, methotrexate or leflunomide Number of claims: 1 Look back timeframe: 90 days	
Label Name	GCN
ARAVA 10MG TABLET	67031
ARAVA 20MG TABLET	67032
AZATHIOPRINE 50MG TABLET	46771
CYCLOPHOSPHAMIDE 25MG CAPSULE	35317
CYCLOPHOSPHAMIDE 50MG CAPSULE	35318
LEFLUNOMIDE 10MG TABLET	67031
LEFLUNOMIDE 20MG TABLET	67032
METHOTREXATE 2.5MG TABLET	38489
METHOTREXATE 50MG/2ML VIAL	18936
OTREXUP 10MG/0.4ML AUTO-INJ	35427
OTREXUP 15MG/0.4ML AUTO-INJ	35428
OTREXUP 20MG/0.4ML AUTO-INJ	35437
OTREXUP 25MG/0.4ML AUTO-INJ	35438
RASUVO 10MG/0.2ML AUTOINJ	36847
RASUVO 12.5MG/0.25ML AUTOINJ	36848
RASUVO 15MG/0.3ML AUTOINJ	36849
RASUVO 17.5MG/0.35ML AUTOINJ	36851
RASUVO 20MG/0.4ML AUTOINJ	35437
RASUVO 22.5MG/0.45ML AUTOINJ	36852
RASUVO 25MG/0.5ML AUTOINJ	36853
RASUVO 30MG/0.6ML AUTOINJ	36855
RASUVO 7.5MG/0.15ML AUTOINJ	36846
TREXALL 10MG TABLET	06484
TREXALL 15MG TABLET	13135
TREXALL 5MG TABLET	13134
TREXALL 7.5MG TABLET	38485
XATMEP 2.5MG/ML ORAL SOLUTION	43319

Claim for an intranasal corticosteroid Required days supply: 30 Look back timeframe: 90 days	
Label Name	GCN
BECONASE AQ 0.042% SPRAY	47100
BUDESONIDE 32MCG NASAL SPRAY	92231
DYMISTA NASAL SPRAY	32099
FLUNISOLIDE 0.025% SPRAY	34280
FLUTICASONE PROP 50MCG SPRAY	62263
MOMETASONE FUROATE 50MGCG SPRY	71431
NASONEX 50MCG NASAL SPRAY	71431
QNASL CHILDRENS 40MCG SPRAY	37654
QNASL 80MCG NASAL SPRAY	31769
TRIAMCINOLONE 55MCG NASAL SPRAY	36145
XHANCE 93MCG NASAL SPRAY	43878

Diagnosis of a helminth infection Required diagnoses: 1 Look back timeframe: 180 days	
ICD-10 Code	Description
B650	SCHISTOSOMIASIS DUE TO SCHISTOSOMA HAEMATOBIUM [URINARY SCHISTOSOMIASIS]
B651	SCHISTOSOMIASIS DUE TO SCHISTOSOMA MANSONI [INTESTINAL SCHISTOSOMIASIS]
B652	SCHISTOSOMIASIS DUE TO SCHISTOSOMA JAPONICUM
B653	CERCARIAL DERMATITIS
B658	OTHER SCHISTOSOMIASIS
B659	SCHISTOSOMIASIS, UNSPECIFIED
B660	OPISTHORCHIASIS
B661	CLONORCHIASIS
B662	DICROCELIASIS
B663	FASCIOLIASIS
B664	PARAGONIMIASIS
B665	FASCIOLOPSIASIS
B668	OTHER SPECIFIED FLUKE INFECTIONS
B669	FLUKE INFECTION, UNSPECIFIED
B670	ECHINOCOCCUS GRANULOSUS INFECTION OF LIVER
B671	ECHINOCOCCUS GRANULOSUS INFECTION OF LUNG

Diagnosis of a helminth infection Required diagnoses: 1 Look back timeframe: 180 days	
ICD-10 Code	Description
B672	ECHINOCOCCUS GRANULOSUS INFECTION OF BONE
B6731	ECHINOCOCCUS GRANULOSUS INFECTION, THYROID GLAND
B6732	ECHINOCOCCUS GRANULOSUS INFECTION, MULTIPLE SITES
B6739	ECHINOCOCCUS GRANULOSUS INFECTION, OTHER SITES
B674	ECHINOCOCCUS GRANULOSUS INFECTION, UNSPECIFIED
B675	ECHINOCOCCUS MULTILOCULARIS INFECTION OF LIVER
B6761	ECHINOCOCCUS MULTILOCULARIS INFECTION, MULTIPLE SITES
B6769	ECHINOCOCCUS MULTILOCULARIS INFECTION, OTHER SITES
B677	ECHINOCOCCUS MULTILOCULARIS INFECTION, UNSPECIFIED
B678	ECHINOCOCCOSIS, UNSPECIFIED, OF LIVER
B6790	ECHINOCOCCOSIS, UNSPECIFIED
B6799	OTHER ECHINOCOCCOSIS
B680	TAENIA SOLIUM TAENIASIS
B681	TAENIA SAGINATA TAENIASIS
B689	TAENIASIS, UNSPECIFIED
B690	CYSTICERCOSIS OF CENTRAL NERVOUS SYSTEM
B691	CYSTICERCOSIS OF EYE
B6981	MYOSITIS IN CYSTICERCOSIS
B6989	CYSTICERCOSIS OF OTHER SITES
B699	CYSTICERCOSIS, UNSPECIFIED
B700	DIPHYLLOBOTHRIASIS
B701	SPARGANOSIS
B710	HYMENOLEPIASIS
B711	DIPYLIDIASIS
B718	OTHER SPECIFIED CESTODE INFECTIONS
B719	CESTODE INFECTION, UNSPECIFIED
B72	DRACUNCULIASIS
B7300	ONCHOCERCIASIS WITH EYE INVOLVEMENT, UNSPECIFIED
B7301	ONCHOCERCIASIS WITH ENDOPHTHALMITIS
B7302	ONCHOCERCIASIS WITH GLAUCOMA
B7309	ONCHOCERCIASIS WITH OTHER EYE INVOLVEMENT
B731	ONCHOCERCIASIS WITHOUT EYE DISEASE
B740	FILARIASIS DUE TO WUCHERERIA BANCROFTI
B741	FILARIASIS DUE TO BRUGIA MALAYI
B742	FILARIASIS DUE TO BRUGIA TIMORI
B743	LOIASIS

Diagnosis of a helminth infection Required diagnoses: 1 Look back timeframe: 180 days	
ICD-10 Code	Description
B744	MANSONELLIASIS
B748	OTHER FILARIASES
B749	FILARIASIS, UNSPECIFIED
B75	TRICHINELLOSIS
B760	ANCYLOSTOMIASIS
B761	NECATORIASIS
B768	OTHER HOOKWORM DISEASES
B769	HOOKWORM DISEASE, UNSPECIFIED
B770	ASCARIASIS WITH INTESTINAL COMPLICATIONS
B7781	ASCARIASIS PNEUMONIA
B7789	ASCARIASIS WITH OTHER COMPLICATIONS
B779	ASCARIASIS, UNSPECIFIED
B780	INTESTINAL STRONGYLODIASIS
B781	CUTANEOUS STRONGYLODIASIS
B787	DISSEMINATED STRONGYLODIASIS
B789	STRONGYLODIASIS, UNSPECIFIED
B79	TRICHURIASIS
B80	ENTEROBIASIS
B810	ANISAKIASIS
B811	INTESTINAL CAPILLARIASIS
B812	TRICHOSTRONGYLIASIS
B813	INTESTINAL ANGIOSTRONGYLIASIS
B814	MIXED INTESTINAL HELMINTHIASES
B818	OTHER SPECIFIED INTESTINAL HELMINTHIASES
B820	INTESTINAL HELMINTHIASIS, UNSPECIFIED
B829	INTESTINAL PARASITISM, UNSPECIFIED
B830	VISCERAL LARVA MIGRANS
B831	GNATHOSTOMIASIS
B832	ANGIOSTRONGYLIASIS DUE TO PARASTRONGYLUS CANTONENSIS
B833	SYNGAMIASIS
B834	INTERNAL HIRUDINIASIS
B838	OTHER SPECIFIED HELMINTHIASES
B839	HELMINTHIASIS, UNSPECIFIED

History of an anthelmintic agent	
Number of claims: 1	
Look back timeframe: 180 days	
Label Name	GCN
ALBENDAZOLE 200 MG TABLET	53290
ALBENZA 200 MG TABLET	53290
BILTRICIDE 600 MG TABLET	08490
EMVERM 100 MG TABLET CHEW	43181
IVERMECTIN 3 MG TABLET	93064
PRAZIQUANTEL 600 MG TABLET	08490
STROMECTOL 3 MG TABLET	93064



Monoclonal Antibodies (Fasenra and Nucala)

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2020. Available at www.clinicalpharmacology.com. Accessed on April 24, 2020.
2. Fasenra Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. October 2019.
3. Nucala Prescribing Information. GlaxoSmithKline LLC. Philadelphia, PA. July 2021.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
04/24/2020	Initial publication and presentation to DUR Board
05/26/2020	Removed GCN for Fasenra syringe
02/01/2021	<p>Updated Fasenra criteria:</p> <ul style="list-style-type: none">Updated lookback to 180 days in question #6 on criteria logic and logic diagramClarified question #7 and #8 – added greater than 1 syringe or pen per 56 days is equivalent to 0.018 units/day and greater than 1 syringe or pen per 28 days is equivalent to 0.036 units/day on criteria logic and logic diagram <p>Updated Nucala criteria:</p> <ul style="list-style-type: none">Added diagnosis of hypereosinophilic syndrome (HES) and age check to criteria logic and logic diagramAdded HES diagnosis table <p>Updated references</p>
06/08/2021	Updated Nucala criteria: <ul style="list-style-type: none">Removed approval criteria for clients aged 6-11 years; prescribing information states that prefilled autoinjector and prefilled syringe are only for use in adults and adolescents ages 12 and older
08/09/2021	Updated Nucala criteria: <ul style="list-style-type: none">Added diagnosis of chronic rhinosinusitis with nasal polyps for clients \geq 18 years of age that had an inadequate response to intranasal corticosteroids
05/09/2024	Added GCN for Nucala (52416) to Drugs Requiring PA table and to the Duplicate Monoclonal Antibody Therapy table