

**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)

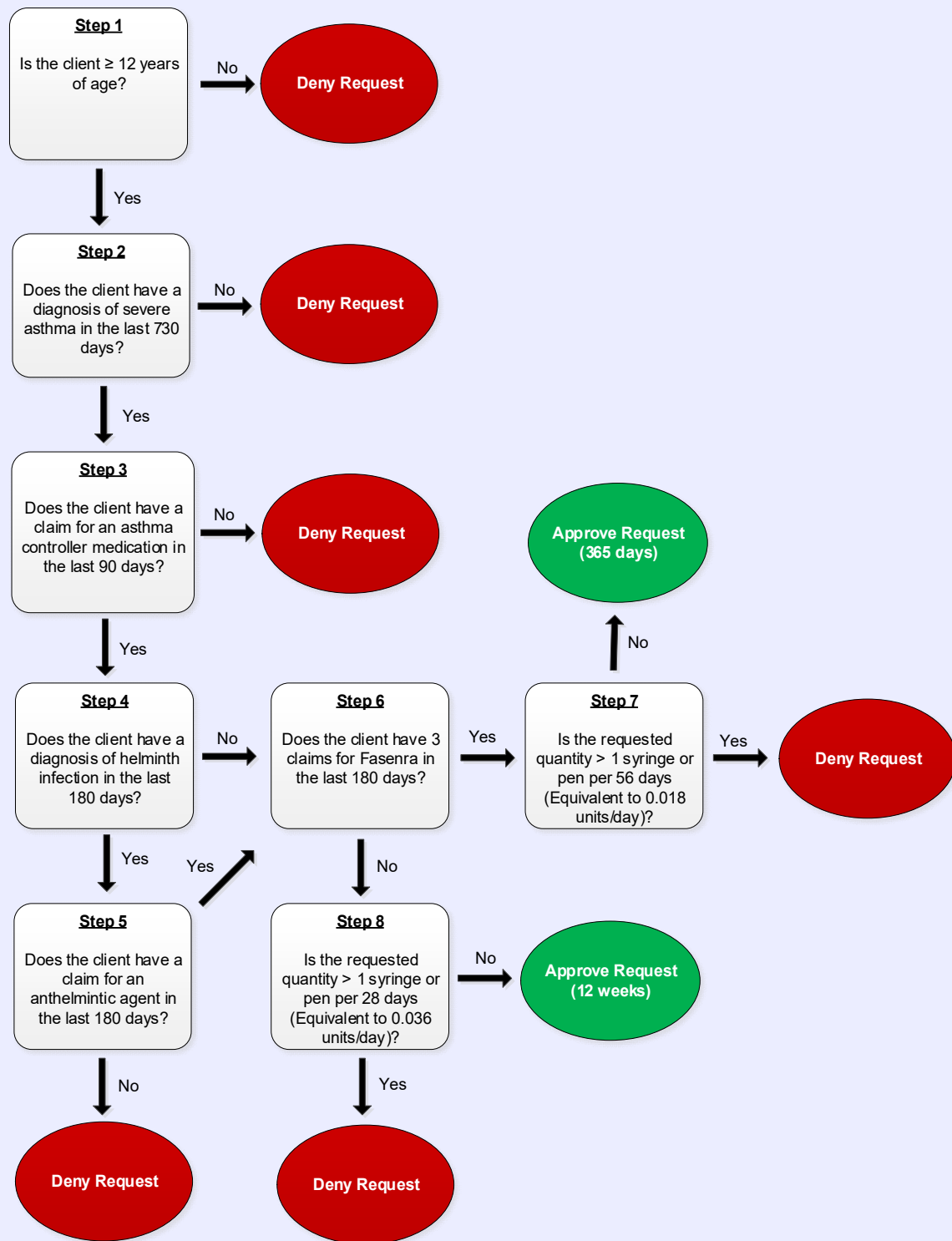
Clinical Criteria Logic

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

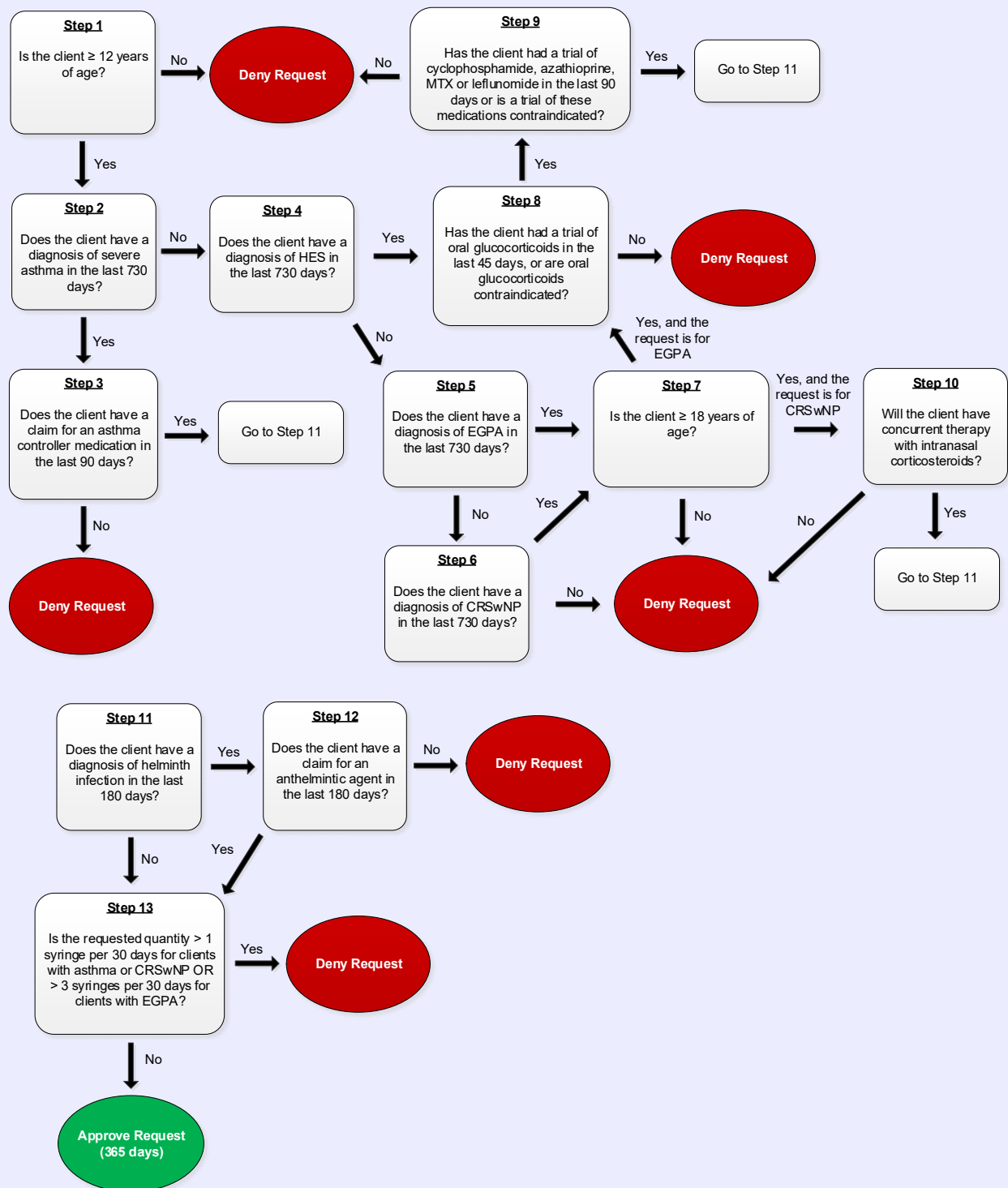
1. Is the client greater than or equal to (\geq) 12 years of age?
☐ Yes (Go to #2)
☐ No (Deny)
2. Does the client have a **diagnosis of severe asthma** in the last 730 days?
☐ Yes (Go to #3)
☐ No (Go to #4)
3. Does the client have a claim for an **asthma controller medication** in the last 90 days?
☐ 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)

Clinical Criteria Logic Diagram





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 HAEMATOBIMUM [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 STRONGYLOIDIASIS |
| B781 | CUTANEOUS STRONGYLOIDIASIS |
| B787 | DISSEMINATED STRONGYLOIDIASIS |
| B789 | STRONGYLOIDIASIS, 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 |
| STROMEKTOL 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 diagram Clarified 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 diagram Added HES diagnosis table <p>Updated references</p> |
| 06/08/2021 | <p>Updated Nucala criteria:</p> <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 | <p>Updated Nucala criteria:</p> <ul style="list-style-type: none"> Added diagnosis of chronic rhinosinusitis with nasal polyps for clients ≥ 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 |