



# Texas Prior Authorization Program Clinical Criteria

## **Monoclonal Antibody Agents**

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

#### **Clinical Information Included in this Document**

#### Adbry (Tralokinumab-ldrm)

- **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); provided when applicable
- References: clinical publications and sources relevant to this clinical criteria

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

#### **Dupixent (Dupilumab)**

- **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); provided when applicable
- **References:** clinical publications and sources relevant to this clinical criteria

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#### Ebglyss (lebrikizumab-lbkz)

- **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); provided when applicable
- References: clinical publications and sources relevant to this clinical criteria

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#### 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

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#### Nucala (Mepolizumab)

- **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

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#### **Tezspire** (**Tezepelumab-ekko**)

- **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

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#### Xolair (Omalizumab)

- 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.

#### **Revision Notes**

Added criteria for Ebglyss as approved by the DURB Board



## Monoclonal Antibody Agents Adbry (Tralokinumab-Idrm)

## **Drugs Requiring Prior Authorization**

Drugs Requiring Price	or Authorization
Label Name	GCN
ADBRY 150 MG/ML SYRINGE	51749
ADBRY 300 MG/2 ML AUTOINJECTOR	55922



# **Monoclonal Antibody Agents Adbry (Tralokinumab-Idrm)**

**Clinical Criteria Logic** 

### Initial Requests:

1.	Is the request for 150 mg/mL syringe? [ ] Yes – Go to #3 [ ] No – Go to #2
2.	Is the request for 300 mg/2 mL autoinjector? [ ] Yes – Go to #4 [ ] No – Deny
3.	Is the client greater than or equal to (≥) 12 years of age?  [ ] Yes - Go to #5  [ ] No - Deny
4.	Is the client greater than or equal to (≥) 18 years of age?  [ ] Yes – Go to #5  [ ] No – Deny
5.	Does the client have a diagnosis of moderate to severe <b>atopic dermatitis</b> in the last 365 days that involves greater than or equal to (≥) 10% of the client's body surface area? [Manual]  [] Yes - Go to #6  [] No - Deny
5.	Does the client have a claim for a <b>topical corticosteroid</b> and either <b>crisaborole, pimecrolimus or tacrolimus (topical)</b> in the last 365 days? [ ] Yes - Go to #7 [ ] No - Deny
7.	Does the client have a diagnosis of <b>helminth infection</b> in the last 180 days? [ ] Yes – Go to #8 [ ] No – Approve (365 days)
3.	Does the client have a claim for an <b>anthelmintic agent</b> in the last 180 days? [ ] Yes – Approve (365 days) [ ] No – Deny

#### Renewal Requests:

1. Does the client have a diagnosis of **atopic dermatitis** in the last 365 days?

[ ] Yes – Go to #2 [ ] No – Deny

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

[ ] Yes – Go to #3 [ ] No – Go to #4

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

[ ] Yes – Go to #4 [ ] No – Deny

4. Does the client continue to show improvement? [Manual step]

[] Yes - Approve (365 days)

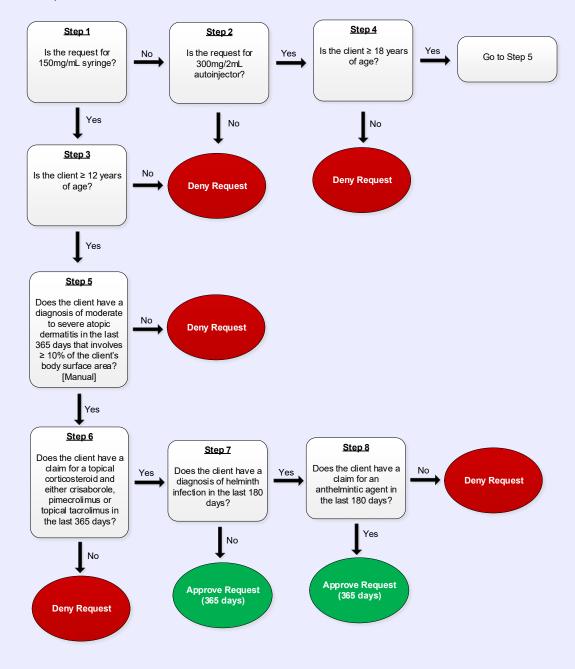
[] No – Deny



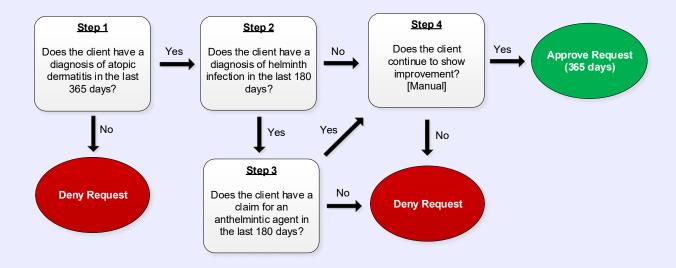
# Monoclonal Antibody Agents Adbry (Tralokinumab-Idrm)

**Clinical Criteria Logic Diagram** 

#### **Initial Requests:**



### Renewal Requests:





# Monoclonal Antibody Agents Dupixent (Dupilumab)

### **Drugs Requiring Prior Authorization**

Drugs Requiring Prior Authorization	
Label Name	GCN
DUPIXENT 100 MG/0.67 ML SYRINGE	51385
DUPIXENT 200 MG/1.14 ML PEN	48785
DUPIXENT 200 MG/1.14 ML SYRINGE	45522
DUPIXENT 300 MG/2 ML PEN	48277
DUPIXENT 300 MG/2 ML SYRINGE	43222



# Monoclonal Antibody Agents Dupixent (Dupilumab)

**Clinical Criteria Logic** 

Initial Requests:

1.	Is the client greater than or equal to (≥) 6 months of age?  [ ] Yes - Go to #2  [ ] No - Deny
2.	Does the client have a diagnosis of moderate to severe <b>atopic dermatitis</b> in the last 365 days that involves greater than or equal to (≥) 10% of the client's body surface area? [Manual step]  [] Yes – Go to #3  [] No – Go to #4
3.	Does the client have a claim for a <b>topical corticosteroid</b> and <b>crisaborole</b> , <b>pimecrolimus</b> , <b>or tacrolimus</b> ( <b>topical</b> ) in the last 365 days?  [ ] Yes – Approve (365 days)  [ ] No – Go to #4
4.	Is the client greater than or equal to (≥) 6 years of age?  [ ] Yes - Go to #5  [ ] No - Go to #7
5.	Does the client have a diagnosis of <b>moderate-to-severe asthma</b> in the last 365 days? [ ] Yes – Go to #6 [ ] No – Go to #7
5.	Does the client have at least 30 days supply of an <b>oral</b> or <b>inhaled corticosteroid</b> in the last 60 days?  [ ] Yes – Approve (365 days)  [ ] No – Go to #7
7.	Is the client greater than or equal to (≥) 1 year of age? [] Yes - Go to #8 [] No - Go to#10
3.	Does the client have a diagnosis of <b>eosinophilic esophagitis</b> in the last 365 days?  [ ] Yes – Go to #9 [ ] No – Go to #10
9.	Does the client weigh greater than or equal to (≥) 15 kg? [Manual] [ ] Yes – Approve (365 days) [ ] No – Go to #10

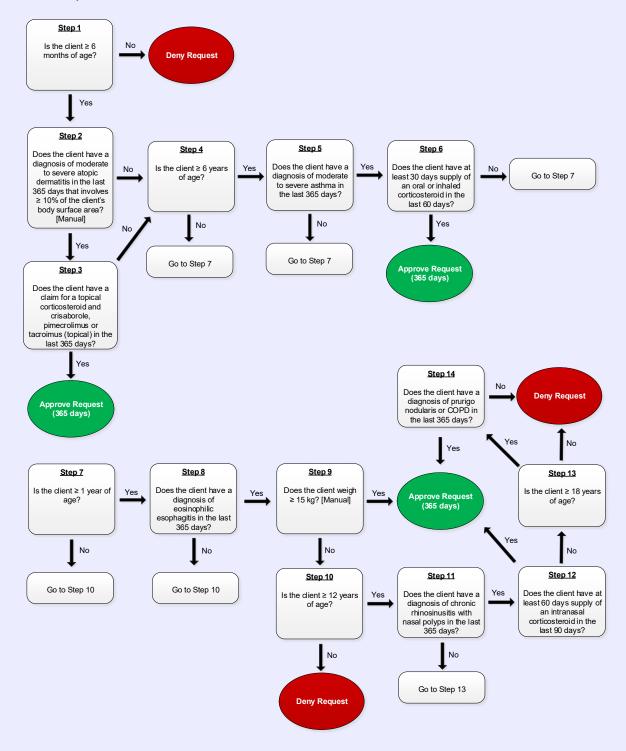
10.Is the client greater than or equal to (≥) 12 years of age? [] Yes - Go to #11 [] No - Deny	
<ul> <li>11.Does the client have a diagnosis of chronic rhinosinusitis with nasal poin the last 365 days?</li> <li>[] Yes - Go to #12</li> <li>[] No - Go to #13</li> </ul>	lyps
<ul> <li>12.Does the client have at least 60 days supply of an intranasal corticostero the last 90 days?</li> <li>[ ] Yes - Approve (365 days)</li> <li>[ ] No - Go to #13</li> </ul>	<b>oid</b> in
13.Is the client greater than or equal to (≥) 18 years of age? [] Yes - Go to #14 [] No - Deny	
14.Does the client have a diagnosis of <b>prurigo nodularis</b> or <b>chronic obstruction pulmonary disease (COPD)</b> in the last 365 days?  [ ] Yes – Approve (365 days)  [ ] No – Deny	tive
Renewal Requests:	
<ol> <li>Does the client have a diagnosis of atopic dermatitis, asthma, chronic obstructive pulmonary disease, chronic rhinosinusitis with nasal po eosinophilic esophagitis or prurigo nodularis in the last 365 days?         <ul> <li>Yes - Go to #2</li> <li>No - Deny</li> </ul> </li> </ol>	lyps,
<ul><li>2. Does the client continue to show improvement? [Manual step]</li><li>[ ] Yes – Approve (365 days)</li><li>[ ] No – Deny</li></ul>	



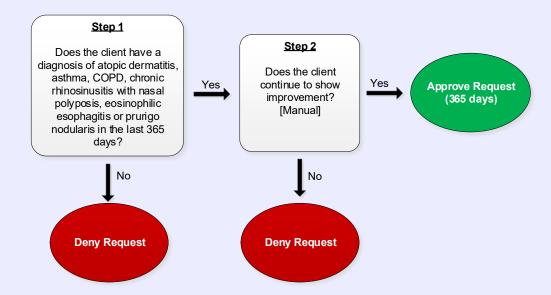
# Monoclonal Antibody Agents Dupixent (Dupilumab)

**Clinical Criteria Logic Diagram** 

#### Initial Requests:



### Renewal Requests:





## Monoclonal Antibody Agents Ebglyss (lebrikizumab-lbkz)

### **Drugs Requiring Prior Authorization**

Drugs Requiring	Prior Authorization
Label Name	GCN
EBGLYSS 250 MG/2 ML PEN	55845
EBGLYSS 250 MG/2 ML SYRINGE	56133



## Monoclonal Antibody Agents Ebglyss (lebrikizumab-lbkz)

**Clinical Criteria Logic** 

Initial Requests:

L.	Is the client greater than or equal to (≥) 12 years of age?  [ ] Yes – Go to #2  [ ] No – Deny
2.	Does the client have a diagnosis of moderate to severe <b>atopic dermatitis</b> in the last 365 days that involves greater than or equal to (≥) 10% of the client's body surface area? [Manual]  [ ] Yes - Go to #3  [ ] No - Deny
3.	Does the client have a claim for a <b>topical corticosteroid</b> in the last 365 days? [ ] Yes – Go to #4 [ ] No – Deny
1.	Does the client have a claim for <b>crisaborole</b> , <b>pimecrolimus or tacrolimus</b> ( <b>topical</b> ) in the last 365 days?  [ ] Yes – Go to #5 [ ] No – Deny
5.	Does the client have a <b>diagnosis of helminth infection</b> in the last 180 days? [ ] Yes – Go to #6 [ ] No – Go to #7
5.	Does the client have a claim for an <b>anthelmintic agent</b> in the last 180 days? [ ] Yes – Go to #7 [ ] No – Deny
7.	Will the client have concurrent therapy with another <b>monoclonal antibody agent?</b> [ ] Yes - Deny [ ] No - Approve (365 days)

#### Renewal Requests:

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

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

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[ ] Yes – Go to #3
[ ] No – Deny
```

3. Will the client have concurrent therapy with another **monoclonal antibody** 

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[ ] Yes – Deny
[ ] No – Go to #4
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4. Does the client continue to show improvement or stabilization? [Manual]

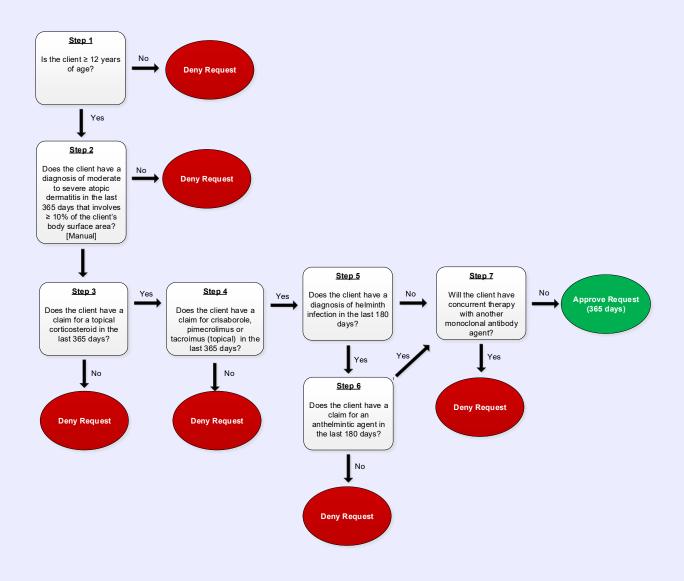
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[ ] Yes – Approve (365 days)
[ ] No – Deny
```



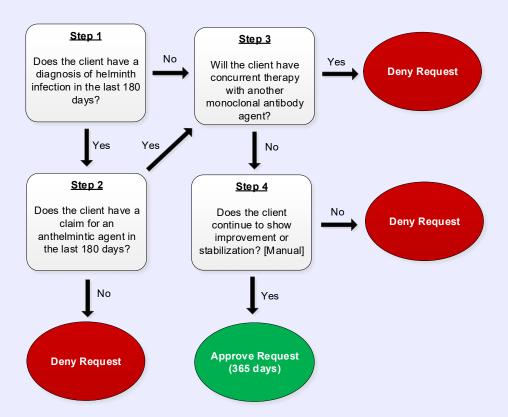
## Monoclonal Antibody Agents Ebglyss (lebrikizumab-lbkz)

**Clinical Criteria Logic Diagram** 

#### **Initial Request:**



### Renewal Request:





## Monoclonal Antibody Agents Fasenra (Benralizumab)

### **Drugs Requiring Prior Authorization**

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



## Monoclonal Antibody Agents Fasenra (Benralizumab)

**Clinical Criteria Logic** 

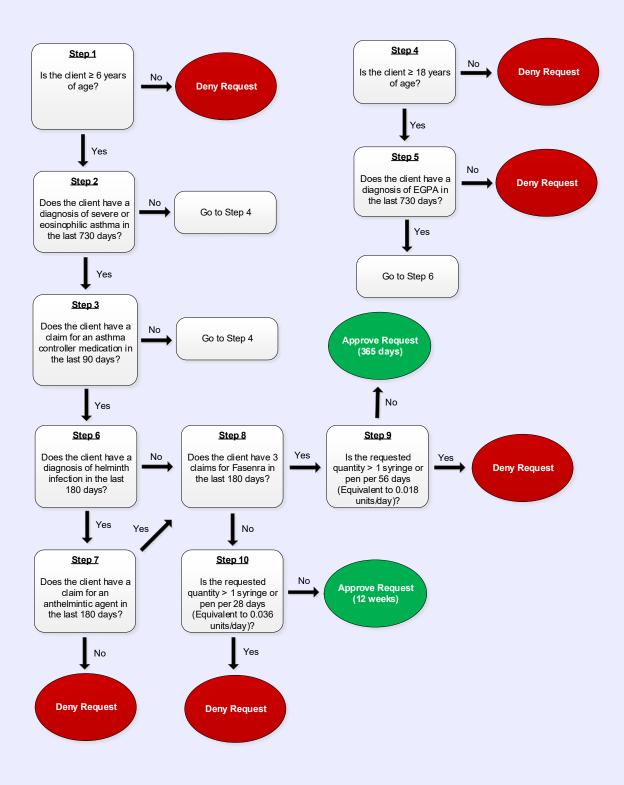
1.	Is the client greater than or equal to (≥) 6 years of age?  [ ] Yes - Go to #2  [ ] No - Deny
2.	Does the client have a diagnosis of <b>severe asthma</b> or <b>eosinophilic asthma</b> in the last 730 days?  [ ] Yes - Go to #3  [ ] No - Go to #4
3.	Does the client have a claim for an <b>asthma controller medication</b> in the last 90 days?  [ ] Yes - Go to #6 [ ] No - Go to #4
4.	Is the client greater than or equal to (≥) 18 years of age?  [ ] Yes - Go to #5  [ ] No - Deny
5.	Does the client have a diagnosis of <b>eosinophilic granulomatosis with polyangiitis (EGPA)</b> in the last 730 days?  [ ] Yes - Go to #6 [ ] No - Deny
5.	Does the client have a diagnosis of <b>helminth infection</b> in the last 180 days? [ ] Yes – Go to #7 [ ] No – Go to #8
7.	Does the client have a claim for an <b>anthelmintic agent</b> in the last 180 days? [ ] Yes – Go to #8 [ ] No – Deny
3.	Does the client have 3 claims for Fasenra (benralizumab) in the last 180 days? [ ] Yes – Go to #9 [ ] No – Go to #10
9.	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)

10.1s the requested quantity greater	tnan (>) 1 syringe or pen per 28 days
(Equivalent to 0.036 units/day)?	
[ ] Yes – Deny	
[ ] No – Approve (12 weeks)	



## Monoclonal Antibody Agents Fasenra (Benralizumab)

**Clinical Criteria Logic Diagram** 





# Monoclonal Antibody Agents Nucala (Mepolizumab)

## **Drugs Requiring Prior Authorization**

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



# Monoclonal Antibody Agents Nucala (Mepolizumab)

**Clinical Criteria Logic** 

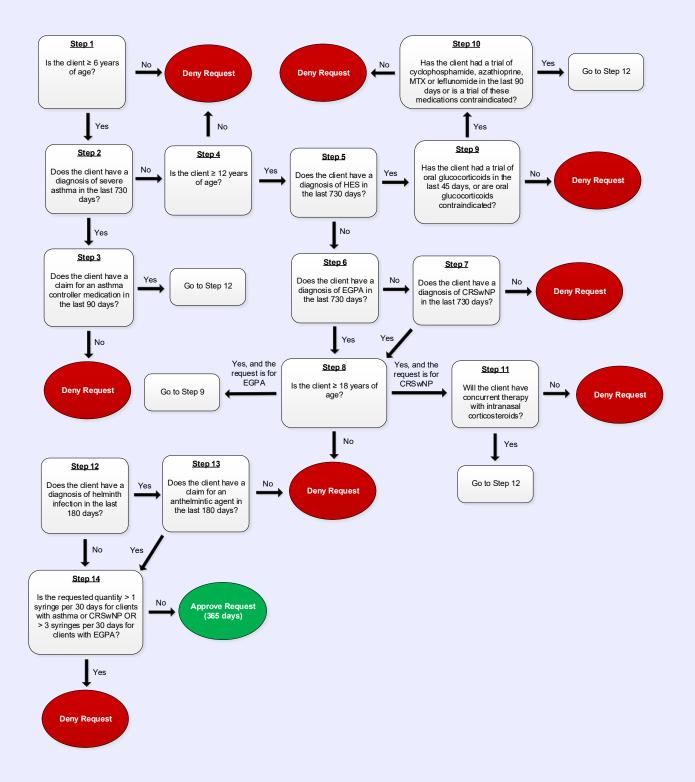
1.	Is the client greater than or equal to (≥) 6 years of age?  [ ] Yes - Go to #2  [ ] No - Deny
2.	Does the client have a diagnosis of <b>severe asthma</b> in the last 730 days? [ ] Yes – Go to #3 [ ] No – Go to #4
3.	Does the client have a claim for an <b>asthma controller medication</b> in the last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

10.Has the client had a <b>trial of cyclophosphamide</b> , <b>azathioprine</b> , <b>methotrexate or leflunomide</b> in the last 90 days, or is a trial of these medications contraindicated?  [ ] Yes - Go to #12 [ ] No - Deny	
11.Will the client have concurrent therapy with <b>intranasal corticosteroids</b> ?  [ ] Yes - Go to #12 [ ] No - Deny	
12.Does the client have a diagnosis of <b>helminth infection</b> in the last 180 days?  [ ] Yes – Go to #13  [ ] No – Go to #14	
13.Does the client have a claim for an <b>anthelmintic agent</b> in the last 180 days? [ ] Yes – Go to #14 [ ] No – Deny	
14.Is the requested quantity greater than (>) 1 syringe per 30 days for clients wire asthma or CRSwNP OR greater than (>) 3 syringes per 30 days for clients with EGPA or HES? <ul> <li>Yes - Deny</li> <li>No - Approve (365 days)</li> </ul>	



# Monoclonal Antibody Agents Nucala (Mepolizumab)

### **Clinical Criteria Logic Diagram**





## Monoclonal Antibody Agents Tezspire (Tezepelumab-ekko)

### **Drugs Requiring Prior Authorization**

Drugs Requiring Prior Authorization	
Label Name	GCN
TEZSPIRE 210 MG/1.91 ML PEN	53116



# Monoclonal Antibody Agents Tezspire (Tezepelumab-ekko)

**Clinical Criteria Logic** 

#### Initial Criteria:

1.	Is the client greater than or equal to (≥) 12 years of age?  [ ] Yes – Go to #2  [ ] No – Deny
2.	Does the client have a diagnosis of <b>severe asthma</b> in the last 730 days? [ ] Yes – Go to #3 [ ] No – Deny
3.	Does the client have a claim for an <b>asthma controller medication</b> in the last 90 days?  [ ] Yes – Go to #4  [ ] No – Deny
4.	Does the client have a diagnosis of <b>helminth infection</b> in the last 180 days? [ ] Yes – Go to #5 [ ] No – Go to #6
5.	Does the client have a claim for an <b>anthelmintic agent</b> in the last 180 days? [ ] Yes – Go to #6 [ ] No – Deny
6.	Is the requested quantity greater than (>) 1 pen per 28 days? [ ] Yes - Deny [ ] No - Approve (365 days)

#### Renewal Criteria:

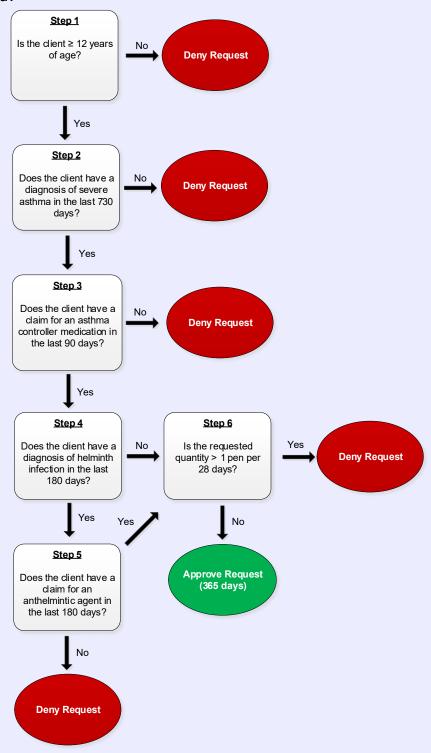
1.	Does the client have a diagnosis of <b>severe asthma</b> in the last 730 days? [ ] Yes – Go to #2 [ ] No – Deny
2.	Does the client have a diagnosis of <b>helminth infection</b> in the last 180 days? [ ] Yes – Go to #3 [ ] No – Go to #4
3.	Does the client have a claim for an <b>anthelmintic agent</b> in the last 180 days? [ ] Yes – Go to #4 [ ] No – Deny
4.	Is the requested quantity greater than (>) 1 pen per 28 days?  [] Yes - Deny [] No - Approve (365 days)



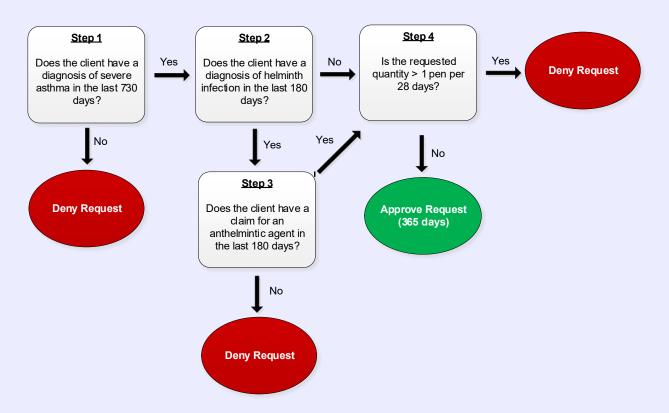
## Monoclonal Antibody Agents Tezspire (Tezepelumab-ekko)

**Clinical Criteria Logic Diagram** 

#### Initial Criteria:



#### Renewal Criteria:





# Monoclonal Antibody Agents Xolair (Omalizumab)

### **Drugs Requiring Prior Authorization**

Drugs Requiring Prior Authorization	
Label Name	GCN
XOLAIR 150 MG/ML AUTOINJECTOR	55223
XOLAIR 150 MG/ML SYRINGE	30556
XOLAIR 300 MG/2 ML AUTOINJECTOR	55225
XOLAIR 300 MG/2 ML SYRINGE	55224
XOLAIR 75 MG/0.5 ML AUTOINJECTOR	55222
XOLAIR 75 MG/0.5 ML SYRINGE	30555



# Monoclonal Antibody Agents Xolair (Omalizumab)

**Clinical Criteria Logic** 

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1. Is the client greater than or equal to (≥) 1 year of age?  [] Yes - Go to #2 [] No - Deny  2. Does the client have a diagnosis of IgE-mediated food allergy in the last 730 days?  [] Yes - Go to #20 [] No - Go to #3  3. Is the client greater than or equal to (≥) 6 years of age?  [] Yes - Go to #4 [] No - Deny  4. Does the client have a diagnosis of moderate to severe persistent asthma in the last 730 days?  [] Yes - Go to #5 [] No - Go to #11  5. Has the client had a positive skin test or in vitro reactivity to a perennial aeroallergen in the last 5 years?  [] Yes - Go to #6 [] No - Go to #11  6. Does the client have at least 60 days therapy with an inhaled corticosteroid (ICS) in the last 90 days OR does the client have an intolerance, hypersensitivity, or contraindication to inhaled corticosteroids?  [] Yes - Go to #7 [] No - Go to #11  7. Does the client have at least 60 days therapy with a long-acting beta agonist (LABA), leukotriene modifier (LTM), long-acting muscarinic antagonist (LAMA) or theophylline in the last 90 days OR does the client have an intolerance or hypersensitivity to all classes listed?  [] Yes - Go to #8 [] No - Go to #11		
days?  [] Yes - Go to #20 [] No - Go to #3  3. Is the client greater than or equal to (≥) 6 years of age?  [] Yes - Go to #4 [] No - Deny  4. Does the client have a diagnosis of moderate to severe persistent asthma in the last 730 days?  [] Yes - Go to #5 [] No - Go to #11  5. Has the client had a positive skin test or in vitro reactivity to a perennial aeroallergen in the last 5 years?  [] Yes - Go to #6 [] No - Go to #11  6. Does the client have at least 60 days therapy with an inhaled corticosteroid (ICS) in the last 90 days OR does the client have an intolerance, hypersensitivity, or contraindication to inhaled corticosteroids?  [] Yes - Go to #7 [] No - Go to #11  7. Does the client have at least 60 days therapy with a long-acting beta agonist (LABA), leukotriene modifier (LTM), long-acting muscarinic antagonist (LAMA) or theophylline in the last 90 days OR does the client have an intolerance or hypersensitivity to all classes listed?  [] Yes - Go to #8	1.	[ ] Yes – Go to #2
[] Yes - Go to #4 [] No - Deny  4. Does the client have a diagnosis of moderate to severe persistent asthma in the last 730 days? [] Yes - Go to #5 [] No - Go to #11  5. Has the client had a positive skin test or in vitro reactivity to a perennial aeroallergen in the last 5 years? [] Yes - Go to #6 [] No - Go to #11  6. Does the client have at least 60 days therapy with an inhaled corticosteroid (ICS) in the last 90 days OR does the client have an intolerance, hypersensitivity, or contraindication to inhaled corticosteroids? [] Yes - Go to #7 [] No - Go to #11  7. Does the client have at least 60 days therapy with a long-acting beta agonist (LABA), leukotriene modifier (LTM), long-acting muscarinic antagonist (LAMA) or theophylline in the last 90 days OR does the client have an intolerance or hypersensitivity to all classes listed? [] Yes - Go to #8	2.	days? [ ] Yes - Go to #20
the last 730 days?  [] Yes – Go to #5  [] No – Go to #11  5. Has the client had a positive skin test or in vitro reactivity to a perennial aeroallergen in the last 5 years?  [] Yes – Go to #6  [] No – Go to #11  6. Does the client have at least 60 days therapy with an inhaled corticosteroid (ICS) in the last 90 days OR does the client have an intolerance, hypersensitivity, or contraindication to inhaled corticosteroids?  [] Yes – Go to #7  [] No – Go to #11  7. Does the client have at least 60 days therapy with a long-acting beta agonist (LABA), leukotriene modifier (LTM), long-acting muscarinic antagonist (LAMA) or theophylline in the last 90 days OR does the client have an intolerance or hypersensitivity to all classes listed?  [] Yes – Go to #8	3.	[ ] Yes – Go to #4
<ul> <li>aeroallergen in the last 5 years? <ul> <li>Yes - Go to #6</li> <li>No - Go to #11</li> </ul> </li> <li>6. Does the client have at least 60 days therapy with an inhaled corticosteroid (ICS) in the last 90 days OR does the client have an intolerance, hypersensitivity, or contraindication to inhaled corticosteroids? <ul> <li>Yes - Go to #7</li> <li>No - Go to #11</li> </ul> </li> <li>7. Does the client have at least 60 days therapy with a long-acting beta agonist (LABA), leukotriene modifier (LTM), long-acting muscarinic antagonist (LAMA) or theophylline in the last 90 days OR does the client have an intolerance or hypersensitivity to all classes listed? <ul> <li>Yes - Go to #8</li> </ul> </li> </ul>	4.	the last 730 days? [ ] Yes – Go to #5
<ul> <li>(ICS) in the last 90 days OR does the client have an intolerance, hypersensitivity, or contraindication to inhaled corticosteroids? <ul> <li>Yes - Go to #7</li> <li>No - Go to #11</li> </ul> </li> <li>7. Does the client have at least 60 days therapy with a long-acting beta agonist (LABA), leukotriene modifier (LTM), long-acting muscarinic antagonist (LAMA) or theophylline in the last 90 days OR does the client have an intolerance or hypersensitivity to all classes listed? <ul> <li>Yes - Go to #8</li> </ul> </li> </ul>	5.	aeroallergen in the last 5 years? [ ] Yes – Go to #6
(LABA), leukotriene modifier (LTM), long-acting muscarinic antagonist (LAMA) or theophylline in the last 90 days OR does the client have an intolerance or hypersensitivity to all classes listed?  [ ] Yes - Go to #8	6.	(ICS) in the last 90 days OR does the client have an intolerance, hypersensitivity, or contraindication to inhaled corticosteroids?  [ ] Yes - Go to #7
	7.	(LABA), leukotriene modifier (LTM), long-acting muscarinic antagonist (LAMA) or theophylline in the last 90 days OR does the client have an intolerance or hypersensitivity to all classes listed?  [ ] Yes - Go to #8

<ul> <li>8. Is the client's pretreatment IgE level ≥ 30 IU/mL and ≤ 700 IU/mL (12 years and older) OR ≥ 30 IU/mL and ≤ 1300 IU/mL (6 to &lt; 12 years of age)? [Manual]</li> <li>[] Yes - Go to #9</li> <li>[] No - Go to #11</li> </ul>
9. Does the client weigh more than 150kg? [Manual] [] Yes - Go to #11 [] No - Go to #10
10.Is the requested dose (based on the client's pretreatment serum IgE level and body weight) equal to the <b>dose defined in the FDA labeling</b> , not to exceed 375 mg every 2 weeks? [Manual]     [ ] Yes - Go to #21     [ ] No - Go to #11
11.Does the client have a diagnosis of chronic spontaneous urticaria (CSU) in the last 730 days? <ul> <li>[ ] Yes - Go to #12</li> <li>[ ] No - Go to #15</li> </ul>
12.Is the client greater than or equal to (≥) 12 years of age? [ ] Yes - Go to #13 [ ] No - Deny
13.Does the client have at least 60 days therapy with an H1 antihistamine in th last 90 days OR is does the client have an intolerance, hypersensitivity, or contraindication to all H1 antihistamines? <ul> <li>[ ] Yes - Go to #14</li> <li>[ ] No - Go to #15</li> </ul>
14.Is the requested dose equal to the dose defined in the FDA labeling, not to exceed 300 mg every 4 weeks? [Manual] [ ] Yes - Go to #21 [ ] No - Go to #15
15.Does the client have a diagnosis of <b>nasal polyps</b> in the last 730 days? [ ] Yes – Go to #16 [ ] No – Deny
16.Is the client greater than or equal to (≥) 18 years of age? [] Yes - Go to #17 [] No - Deny
17.Does the client have at least 90 days therapy with an <b>intranasal corticosteroid (INC)</b> in the last 120 days OR does the client have an intolerance, hypersensitivity, or contraindication to nasal corticosteroids?  [ ] Yes – Go to #18 [ ] No – Deny

18	Is the client's pretreatment IgE level ≥ 30 IU/mL and ≤ 1500 IU/mL? [Manual] [ ] Yes – Go to #19 [ ] No – Deny
19	D.Does the client weigh more than 150kg? [Manual] [ ] Yes – Deny [ ] No – Go to #20
20	i.Is the requested dose (based on the client's pretreatment serum IgE level and body weight) equal to the <b>dose defined in the FDA labeling</b> , not to exceed 600 mg every 2 weeks? [Manual]  [ ] Yes - Go to #21  [ ] No - Deny
21	.Will the client have concurrent therapy with another <b>monoclonal antibody agent</b> indicated for the treatment of asthma, chronic spontaneous urticaria or nasal polyps?  [] Yes - Deny [] No - Approve (365 days)
Re	enewal Criteria:
1.	Does the client have a diagnosis of <b>IgE-mediated food allergy</b> in the last 730 days?  [ ] Yes – Go to #11 [ ] No – Go to #2
2.	Does the client have a diagnosis of <b>moderate to severe persistent asthma</b> in the last 730 days?  [ ] Yes – Go to #3  [ ] No – Go to #6
3.	Does the client have current therapy with an <b>inhaled corticosteroid</b> that will continue during therapy with Xolair OR does the client have an intolerance, hypersensitivity, or contraindication to inhaled corticosteroids?  [ ] Yes - Go to #4 [ ] No - Go to #6
4.	Does the client weigh more than 150kg? [Manual] [ ] Yes - Go to #6 [ ] No - Go to #5
5.	Is the requested dose (based on the client's pretreatment serum IgE level and body weight) equal to the <b>dose defined in the FDA labeling</b> , not to exceed 375 mg every 2 weeks? [Manual] [ ] Yes - Go to #12 [ ] No - Go to #6

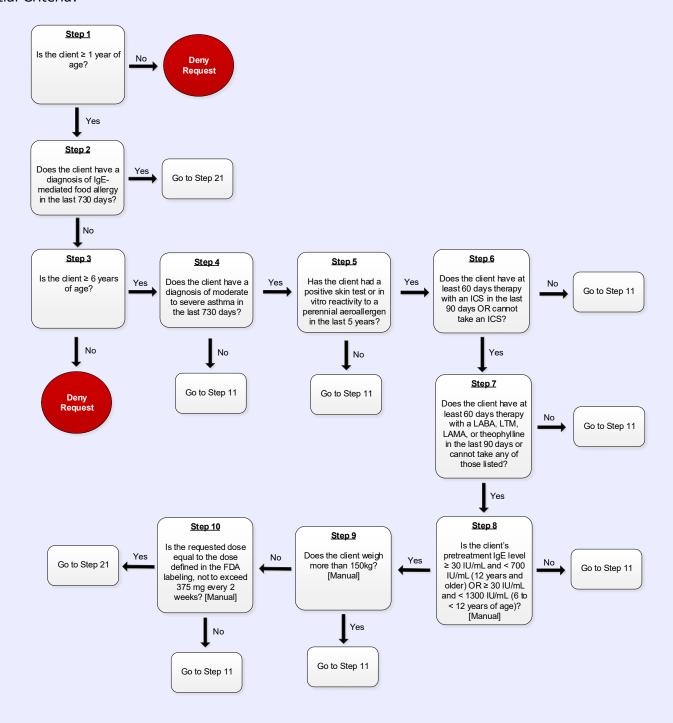
6.	Does the client have a diagnosis of <b>chronic spontaneous urticaria</b> in the last 730 days? [ ] Yes - Go to #7 [ ] No - Go to #8
7.	Is the requested dose equal to the dose defined in the FDA labeling, not to exceed 300 mg every 4 weeks? [Manual] [ ] Yes – Go to #12 [ ] No – Go to #8
8.	Does the client have a diagnosis of <b>nasal polyps</b> in the last 730 days? [ ] Yes – Go to #9 [ ] No – Deny
9.	Does the client have current therapy with an <b>intranasal corticosteroid</b> that will continue during therapy with Xolair OR does the client have an intolerance, hypersensitivity, or contraindication to nasal corticosteroids?  [ ] Yes - Go to #10 [ ] No - Deny
10	Does the client weigh more than 150kg? [Manual] [ ] Yes – Deny [ ] No – Go to #11
11.	Is the requested dose (based on the client's pretreatment serum IgE level and body weight) equal to the <b>dose defined in the FDA labeling</b> , not to exceed 600 mg every 2 weeks? [Manual]  [ ] Yes – Go to #12 [ ] No – Deny
12.	Will the client have concurrent therapy with another <b>monoclonal antibody</b> <pre>agent indicated for the treatment of asthma, chronic spontaneous urticaria or nasal polyps? [ ] Yes - Deny [ ] No - Approve (365 days)</pre>



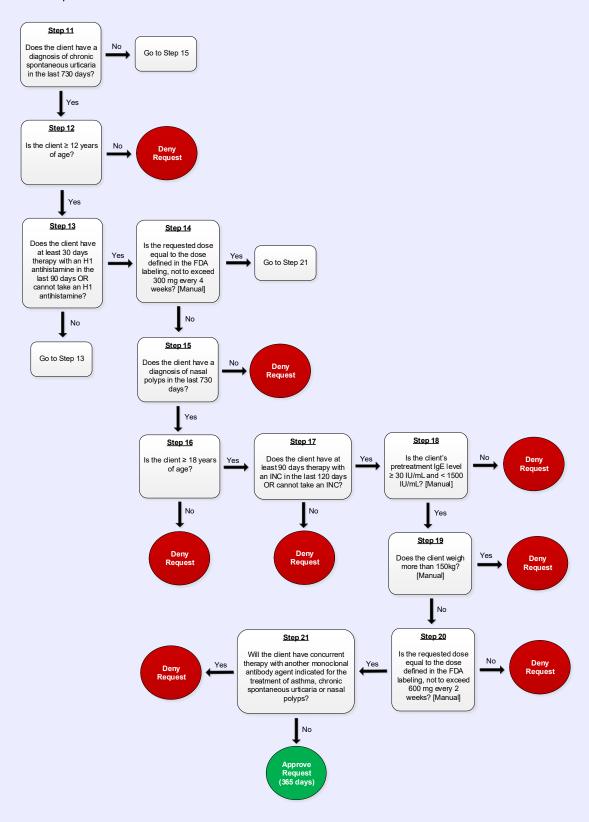
# Monoclonal Antibody Agents Xolair (Omalizumab)

## Clinical Criteria Logic Diagram

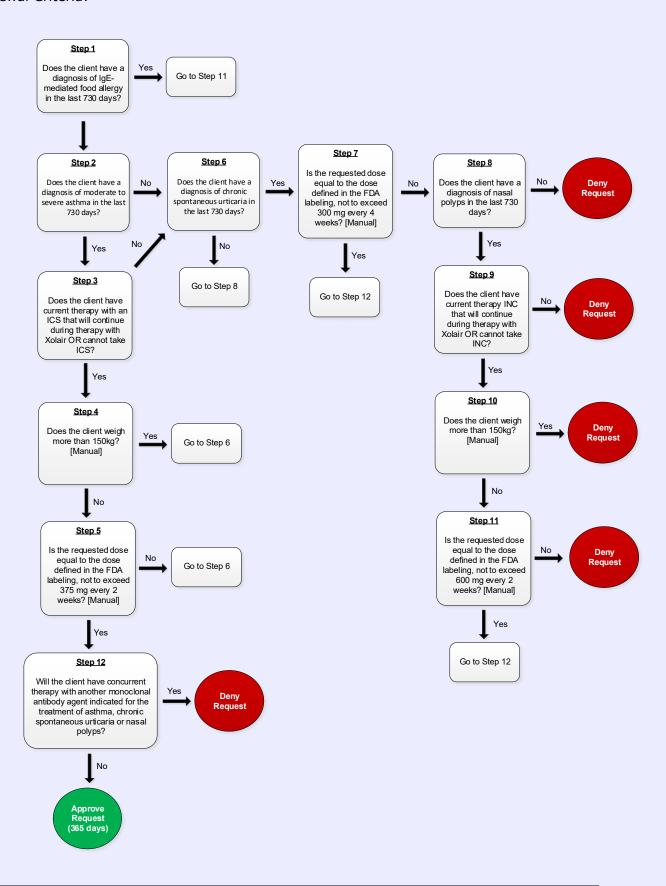
## Initial Criteria:



## Initial Criteria, Continued:



#### Renewal Criteria:





# **Monoclonal Antibodies for Asthma**

## **Clinical Criteria Supporting Tables**

Allergen testing		
Required quantity: 1		
Look back timeframe: 5 years		
ICD-10 Code	ICD-10 Code Description	
Z0182	ENCOUNTER FOR ALLERGY TESTING	

Anthelmintic Agent		
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	

Asthma Controller Medication		
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	
AIRDUO DIGIHALER 113-14MCG	48494	
AIRDUO DIGIHALER 232-14MCG	48495	
AIRDUO DIGIHALER 55-14MCG	48489	
AIRSUPRA 90-80MCG INHALER	53534	
ALVESCO 160 MCG INHALER	24152	
ALVESCO 80 MCG INHALER	24149	
ARMONAIR RESPICLICK 232MCG	42985	
ARMONAIR RESPICLICK 55MCG	42979	

Asthma Controller Medication		
Label Name	GCN	
ARMONAIR DIGIHALER 55MCG	48602	
ARMONAIR DIGIHALER 113 MCG	48604	
ARMONAIR DIGIHALER 232 MCG	48615	
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	
ASMANEX HFA 50 MCG INHALER	47599	
ASMANEX HFA 100 MCG INHALER	37566	
ASMANEX HFA 200 MCG INHALER	37565	
BREO ELLIPTA 100-25MCG INH	34647	
BREO ELLIPTA 200-25MCG INHALER	35808	
BREYNA 160-4.5MCG INHALER	98500	
BREYNA 80-4.5MCG INHALER	98499	
BREZTRI AEROSPHERE INHALER	48435	
BUDESONIDE 0.25MG/2ML INHALATION SUSPENSION	17957	
BUDESONIDE 0.5MG/2ML INHALATION SUSPENSION	17958	
BUDESONIDE 1MG/2ML INHALATION SUSPENSION	62980	
BUDESONIDE-FORMOTEROL 160-4.5MCG	98500	
BUDESONIDE-FORMOTEROL 80-4.5MCG	98499	
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 PROP 100MCG DISKUS	53633	
FLUTICASONE PROP 250MCG DISKUS	53634	
FLUTICASONE PROP 50MCG DISKUS	53635	
FLUTICASONE PROP HFA 110MCG	53636	

Asthma Controller Medication		
Label Name	GCN	
FLUTICASONE PROP HFA 220MCG	53639	
FLUTICASONE PROP HFA 44MCG	53638	
FLUTICASONE-SALMETEROL 55-14	42956	
FLUTICASONE-SALMETEROL 113-14	42957	
FLUTICASONE-SALMETEROL 232-14	42958	
FLUTICASONE-VILANTEROL 100-25	34647	
FLUTICASONE-VILANTEROL 200-25	35808	
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	
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	

Asthma Controller Medication		
Label Name	GCN	
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	
TRELEGY ELLIPTA 100-62.5-25	43921	
TRELEGY ELLIPTA 200-62.5-25	48708	
WIXELA 100-50 INHUB	50584	
WIXELA 250-50 INHUB	50594	
WIXELA 500-50 INHUB	50604	

Moderate to Severe Asthma		
ICD-10 Code	Description	
J4540	MODERATE PERSISTENT ASTHMA UNCOMPLICATED	
J4541	MODERATE PERSISTENT ASTHMA WITH (ACUTE) EXACERBATION	
J4542	MODERATE PERSISTENT ASTHMA WITH STATUS ASTHMATICUS	
J4550	SEVERE PERSISTENT ASTHMA UNCOMPLICATED	
J4551	SEVERE PERSISTENT ASTHMA WITH (ACUTE) EXACERBATION	
J4552	SEVERE PERSISTENT ASTHMA WITH STATUS ASTHMATICUS	
J82	PULMONARY EOSINOPHILIA, NOT ELSEWHERE CLASSIFIED	

Moderate to Severe Persistent Asthma		
ICD-10 Code	Description	
J4540	MODERATE PERSISTENT ASTHMA, UNCOMPLICATED	
J4541	MODERATE PERSISTENT ASTHMA, WITH (ACUTE) EXACERBATION	
J4542	MODERATE PERSISTENT ASTHMA, WITH STATUS ASTHMATICUS	
J4550	SEVERE PERSISTENT ASTHMA, UNCOMPLICATED	
J4551	SEVERE PERSISTENT ASTHMA, WITH (ACUTE) EXACERBATION	
J4552	SEVERE PERSISTENT ASTHMA, WITH STATUS ASTHMATICUS	

Severe Asthma	
ICD-10 Code	Description
J4550	SEVERE PERSISTENT ASTHMA, UNCOMPLICATED
J4551	SEVERE PERSISTENT ASTHMA, WITH (ACUTE) EXACERBATION

Severe Asthma	
ICD-10 Code	Description
J4552	SEVERE PERSISTENT ASTHMA, WITH STATUS ASTHMATICUS

Atopic Dermatitis	
ICD-10 Code	Description
L200	BESNIER'S PRURIGO
L2081	ATOPIC NEURODERMATITIS
L2082	FLEXURAL ECZEMA
L2084	INTRINSIC (ALLERGIC) ECZEMA
L2089	OTHER ATOPIC DERMATITIS
L209	ATOPIC DERMATITIS, UNSPECIFIED

Chronic Spontaneous Urticaria		
ICD-10 Code	Description	
L500	ALLERGIC URTICARIA	
L501	IDIOPATHIC URTICARIA	
L508	OTHER (CHRONIC, RECURRENT) URTICARIA	
L509	UNSPECIFIED URTICARIA	

Chronic Obstructive Pulmonary Disease		
ICD-10 Code	Description	
J440	CHRONIC OBSTRUCTIVE PULMONARY DISEASE WITH (ACUTE) LOWER RESPIRATORY INFECTION	
J441	CHRONIC OBSTRUCTIVE PULMONARY DISEASE WITH (ACUTE) EXACERBATION	
J4489	OTHER SPECIFIED CHRONIC OBSTRUCTIVE PULMONARY DISEASE	
J449	CHRONIC OBSTRUCTIVE PULMONARY DISEASE, UNSPECIFIED	

Crisaborole	
Label Name	GCN
EUCRISA 2% OINTMENT	42792

Crisaborole, Pimecrolimus or topical Tacrolimus		
Label Name	GCN	
ELIDEL 1% CREAM	15348	
EUCRISA 2% OINTMENT	42792	
PIMECROLIMUS 1% CREAM	15348	

Crisaborole, Pimecrolimus or topical Tacrolimus		
Label Name	GCN	
PROTOPIC 0.03% OINTMENT	12289	
PROTOPIC 0.1% OINTMENT	12302	
TACROLIMUS 0.03% OINTMENT	12289	
TACROLIMUS 0.1% OINTMENT	12302	

Cyclophosphamide, Azathioprine, Methotrexate or Leflunomide		
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	

Duplicate Monoclonal Antibody Therapy		
Label Name	GCN	
CINQAIR 100 MG/10 ML VIAL	40873	
DUPIXENT 100 MG/0.67 ML SYRINGE	51385	
DUPIXENT 200 MG/1.14 ML PEN	48785	
DUPIXENT 200 MG/1.14 ML SYRINGE	45522	
DUPIXENT 300 MG/2 ML PEN	48277	
DUPIXENT 300 MG/2 ML SYRINGE	43222	
FASENRA PEN 30 MG/ML	47019	
NUCALA 100 MG/ML AUTO-INJECTOR	46414	
NUCALA 100 MG/ML SYRINGE	46413	
NUCALA 40 MG/0.4 ML SYRINGE	52416	
TEZSPIRE 210 MG/1.91 ML PEN	53116	

Eosinophilic Asthma		
ICD-10 Code	Description	
J8283	EOSINOPHILIC ASTHMA	

Eosinophilic Esophagitis		
ICD-10 Code	Description	
K200	EOSINOPHILIC ESOPHAGITIS	

Eosinophilic Granulomatosis with Polyangiitis		
ICD-10 Code	Description	
M301	POLYARTERITIS WITH LUNG INVOLVEMENT [CHURG-STRAUSS]	

Glucocorticoids, Oral		
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	

Glucocorticoids, Oral		
Label Name	GCN	
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	
PREDNISONE 50MG TABLET	27177	
PREDNISONE 5MG/5ML SOLUTION	27160	
PREDNISONE 5MG/5ML SOLUTION	27161	

H1 antihistamine		
Label Name	GCN	
24HR ALLERGY (LEVOCETIRZN) 5 MG	14901	
ALL DAY ALLERGY 10 MG TABLET	49291	
ALLER-CHLOR 4MG TABLET	46512	
ALLERGY (LORATADINE) 10 MG TAB	60563	
ALLERGY 25 MG CAPSULE	45971	
ALLERGY 4 MG TABLET	46512	
ALLERGY RELIEF 10 MG TAB	60563	
ALLERGY RELIEF 180 MG TABLET	46594	
ALLERGY RELIEF 25 MG SOFTGEL	45971	
ALLERGY RELIEF 25 MG TABLET	46071	
ALLERGY RELIEF 4 MG TABLET	46512	
ALLERGY RELIEF 5 MG/5 ML SOLN	60562	
ALLERGY RELIEF D-12 TABLET	63570	
ALLERGY RELIEF D-24HR TABLET	63577	
ALLERGY RELIEF-D TABLET	13866	

H1 antihistamine		
Label Name	GCN	
ALLERGY RLF (CETRZN) 10 MG TAB	49291	
ALLERGY-CONGEST 12HR 60-120 MG	63565	
BANOPHEN 25 MG CAPSULE	45971	
BANOPHEN 50 MG CAPSULE	45972	
CETIRIZINE HCL 10 MG TABLET	49291	
CETIRIZINE HCL 5 MG TABLET	49292	
CETIRIZINE-PSE ER 5-120 MG TAB	13866	
CHILD ALL DAY ALLERGY 1 MG/ML	49290	
CHILD ALLERGY RELIEF 1 MG/ML	49290	
CHILD ALLERGY RELIEF 5MG/5 ML	60562	
CHILD ALLERGY RLF 12.5 MG/5 ML	48831	
CHILD CETIRIZINE 10 MG CHEW TAB	21771	
CHILD CETIRIZINE 5 MG CHEW TAB	21769	
CHILD CETIRIZINE HCL 1 MG/ML SOL	49290	
CHILD LORATADINE 5 MG/5 ML SOL	60562	
CLARINEX 5 MG TABLET	12762	
CLARINEX-D 12 HR 2.5-120 MG TAB	26558	
CLEMASTINE FUM 2.68 MG TAB	46691	
CYPROHEPTADINE 2 MG/5 ML SYRUP	15803	
CYPROHEPTADINE 4 MG TABLET	15811	
DESLORATADINE 2.5 MG ODT	25439	
DESLORATADINE 5 MG ODT	19716	
DESLORATADINE 5 MG TABLET	12762	
DEXBROMPHENIR-PHENYLEPH 2-10 MG	28379	
DIPHENHIST 25 MG CAPSULE	45971	
DIPHENHYDRAMINE 12.5 MG/5 ML	48831	
DIPHENHYDRAMINE 25 MG CAPSULE	45971	
DIPHENHYDRAMINE 25 MG TABLET	46071	
DIPHENHYDRAMINE 50 MG CAPSULE	45972	
DIPHENHYDRAMINE 6.25 MG/ML	42545	
FEXOFENADINE HCL 180 MG TABLET	46594	
FEXOFENADINE HCL 60 MG TABLET	46593	
FEXOFENADINE PSE ER 60-120 TAB	63565	
GNP LORATADINE 10 MG TABLET	60563	
GS ALLERGY RELIEF 10 MG TABLET	60563	
HYDROXYZINE 10 MG/5 ML SYRUP	13932	
HYDROXYZINE HCL 10 MG TABLET	13941	
HYDROXYZINE HCL 25 MG TABLET	13943	

H1 antihistamine		
Label Name	GCN	
HYDROXYZINE HCL 50 MG TABLET	13944	
HYDROXYZINE PAM 100 MG CAP	13951	
HYDROXYZINE PAM 25 MG CAP	13952	
HYDROXYZINE PAM 50 MG CAP	13953	
LEVOCETIRIZINE 2.5 MG/5 ML SOL	97950	
LEVOCETIRIZINE 5 MG TABLET	14901	
LORATADINE 10 MG TABLET	60563	
LORATADINE 5 MG/5 ML SYRUP	60562	
LORATADINE ALLERGY 5 MG/5 ML	60562	
LORATADINE-D 12 HOUR TABLET	63570	
LORATADINE-D 24HR TABLET	63577	
QC CHILD ALLERGY 12.5 MG/5 ML	48831	
QC COMPLETE ALLERGY 25 MG CAP	45971	
SILADRYL 12.5 MG/5 ML	48831	
SM ALLERGY RELIEF 12.5 MG/5 ML	48831	
SM LORATADINE 5 MG/5 ML SYRUUP	60562	
SM LORATADINE D 24HR TABLET	63577	
VISTARIL 25 MG CAPSULE	13952	
VISTARIL 50 MG CAPSULE	13953	

Helminth Infection	
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

Helminth Infection		
ICD-10 Code	Description	
B670	ECHINOCOCCUS GRANULOSUS INFECTION OF LIVER	
B671	ECHINOCOCCUS GRANULOSUS INFECTION OF LUNG	
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	

Helminth Infection		
ICD-10 Code	Description	
B743	LOIASIS	
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	

Hypereosinophilic Syndrome		
ICD-10 Code	Description	
D72110	IDIOPATHIC HYPEREOSINOPHILIC SYNDROME (IHES)	
D72111	LYMPHOCYTIC VARIANT HYPEREOSINOPHILIC SYNDROME (LHES)	
D72118	OTHER HYPEREOSINOPHILIC SYNDROME	
D72119	HYPEREOSINOPHILIC SYNDROME (HES), UNSPECIFIED	

IgE-mediated food allergy		
ICD-10 Code	Description	
Z91010	ALLERGY TO PEANUTS	
Z91011	ALLERGY TO MILK PRODUCTS	
Z91012	ALLERGY TO EGGS	
Z91013	ALLERGY TO SEAFOOD	
Z91014	ALLERGY TO MAMMALIAN MEATS	
Z91018	ALLERGY TO OTHER FOODS	

Inhaled corticosteroid (ICS)		
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	
AIRDUO DIGIHALER 113-14MCG	48494	
AIRDUO DIGIHALER 232-14MCG	48495	
AIRDUO DIGIHALER 55-14MCG	48489	
AIRSUPRA 90-80MCG INHALER	53534	
ALVESCO 160 MCG INHALER	24152	
ALVESCO 80 MCG INHALER	24149	
ARMONAIR RESPICLICK 232MCG	42985	
ARMONAIR RESPICLICK 55MCG	42979	
ARMONAIR DIGIHALER 55MCG	48602	
ARMONAIR DIGIHALER 113 MCG	48604	
ARMONAIR DIGIHALER 232 MCG	48615	
ARNUITY ELLIPTA 100 MCG INH	37007	
ARNUITY ELLIPTA 200 MCG INH	37008	
ARNUITY ELLIPTA 50 MCG INH	44783	

Inhaled corticosteroid (ICS)		
Label Name	GCN	
ASMANEX HFA 100 MCG INHALER	37566	
ASMANEX HFA 200 MCG INHALER	37565	
ASMANEX HFA 50 MCG INHALER	47599	
ASMANEX TWISTHALER 220 MCG #14	24927	
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	
BREYNA 160-4.5MCG INHALER	98500	
BREYNA 80-4.5MCG INHALER	98499	
BREZTRI AEROSPHERE INHALER	48435	
BUDESONIDE 0.25MG/2ML INHALATION SUSPENSION	17957	
BUDESONIDE 0.5MG/2ML INHALATION SUSPENSION	17958	
BUDESONIDE 1MG/2ML INHALATION SUSPENSION	62980	
DULERA 100 MCG/5 MCG INHALER	28766	
DULERA 200 MCG/5 MCG INHALER	28767	
DULERA 50 MCG/5 MCG INHALER	30139	
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 PROP 100MCG DISKUS	53633	
FLUTICASONE PROP 250MCG DISKUS	53634	
FLUTICASONE PROP 50MCG DISKUS	53635	
FLUTICASONE PROP HFA 110MCG	53636	
FLUTICASONE PROP HFA 220MCG	53639	
FLUTICASONE PROP HFA 44MCG	53638	
FLUTICASONE-SALMETEROL 55-14	42956	
FLUTICASONE-SALMETEROL 113-14	42957	
FLUTICASONE-SALMETEROL 232-14	42958	
FLUTICASONE-VILANTEROL 100-25	34647	
FLUTICASONE-VILANTEROL 200-25	35808	
PULMICORT 0.25 MG/2 ML RESPULE	17957	
PULMICORT 0.5MG/2ML RESPULE	17958	

Inhaled corticosteroid (ICS)		
Label Name	GCN	
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	
TRELEGY ELLIPTA 100-62.5-25	43921	
TRELEGY ELLIPTA 200-62.5-25	48708	
WIXELA 100-50 INHUB	50584	
WIXELA 250-50 INHUB	50594	
WIXELA 500-50 INHUB	50604	

Intranasal Corticosteroid (INC)		
Label Name	GCN	
AZELASTIN-FLUTIC 137-50 MCG SPR	32099	
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	
OMNARIS 50 MCG NASAL SPRAY	97453	
QNASL CHILDRENS 40MCG SPRAY	37654	
QNASL 80MCG NASAL SPRAY	31769	
RYALTRIS 665-25MCG SPRAY	49205	
TRIAMCINOLONE 55MCG NASAL SPRAY	36145	
XHANCE 93MCG NASAL SPRAY	43878	

LABA, LTM, LAMA or theophylline		
Label Name	GCN	
MONTELUKAST SOD 10MG TABLET	94444	
MONTELUKAST SOD 4MG GRANULES	18803	
MONTELUKAST SOD 4MG TAB CHEW	42373	
MONTELUKAST SOD 5MG TAB CHEW	94440	
SEREVENT DISKUS 50MCG	64012	
SINGULAIR 10MG TABLET	94444	

LABA, LTM, LAMA or theophylline							
Label Name	GCN						
SINGULAIR 4MG GRANULES	18803						
SINGULAIR 4MG TABLET CHEW	42373						
SINGULAIR 5MG TABLET CHEW	94440						
SPIRIVA 18 MCG CP-HANDIHALER	17853						
SPIRIVA RESPIMAT 1.25 MCG INH	39587						
SPIRIVA RESPIMAT 2.5 MCG INH	98921						
THEO-24 ER 100 MG CAPSULE	00324						
THEO-24 ER 200 MG CAPSULE	00325						
THEO-24 ER 300 MG CAPSULE	00326						
THEO-24 ER 400 MG CAPSULE	00323						
THEOPHYLLINE 80 MG/15 ML SOLN	01080						
THEOPHYLLINE ER 300 MG TAB	00413						
THEOPHYLLINE ER 400 MG TABLET	00415						
THEOPHYLLINE ER 450 MG TAB	00416						
THEOPHYLLINE ER 600 MG TABLET	00417						
TRELEGY ELLIPTA 100-62.5-25	43921						
TRELEGY ELLIPTA 200-62.5-25	48708						
ZAFIRLUKAST 10MG TABLET	52271						
ZAFIRLUKAST 20MG TABLET	18690						
ZILEUTON ER 600MG TABLET	98822						
ZYFLO CR 600MG TABLET	98822						

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

Prurigo Nodularis							
ICD-10 Code Description							
L281	PRURIGO NODULARIS						

Topical Corticosteroid							
Label Name	GCN						
AMCINONIDE 0.1% CREAM	31490						
AMCINONIDE 0.1% LOTION	31560						

Topical Corticosteroid							
Label Name	GCN						
APEXICON E 0.05% CREAM	67730						
BETAMETHASONE DP 0.05% CRM	31060						
BETAMETHASONE DP 0.05% LOT	31080						
BETAMETHASONE DP 0.05% OINT	31070						
BETAMETHASONE DP AUG 0.05% CRM	31890						
BETAMETHASONE DP AUG 0.05% GEL	32091						
BETAMETHASONE DP AUG 0.05% LOT	30980						
BETAMETHASONE DP AUG 0.05% OIN	31910						
BETAMETHASONE VA 0.1% CREAM	31101						
BETAMETHASONE VALER 0.12% FOAM	32052						
BETAMETHASONE VA 0.1% LOTION	31120						
BETAMETHASONE VALER 0.1% OINTM	31110						
BETA-VAL 0.1% LOTION	31120						
CLOBETASOL 0.05% CREAM	32140						
CLOBETASOL 0.05% GEL	15892						
CLOBETASOL 0.05% OINTMENT	32130						
CLOBETASOL 0.05% SOLUTION	15891						
CLOBETASOL EMOLLIENT 0.05% CRM	34141						
CLOBETASOL PROP 0.05% FOAM	89743						
CLOBEX 0.05% SPRAY	25909						
CLOBEX 0.05% TOPICAL LOTION	34040						
CORMAX 0.05% SOLUTION	15891						
DESOXIMETASONE 0.05% CREAM	31180						
DESOXIMETASONE 0.05% GEL	06120						
DESOXIMETASONE 0.25% CREAM	31181						
DESOXIMETASONE 0.25% OINTMENT	30800						
DIFLORASONE 0.05% CREAM	31470						
DIFLORASONE 0.05% OINTMENT	31480						
DIPROLENE 0.05% LOTION	30980						
DIPROLENE AF 0.05% CREAM	31890						
DIPROLENE 0.05% OINTMENT	31910						
DIPROLENE AF 0.05% CREAM	31890						
FLUOCINONIDE 0.05% CREAM	31390						
FLUOCINONIDE 0.05% GEL	31380						
FLUOCINONIDE 0.05% OINTMENT	31400						
FLUOCINONIDE 0.05% SOLUTION	31401						
FLUOCINONIDE-E 0.05% CREAM	54650						

Topical Corticosteroid							
Label Name	GCN						
FLUOCINONIDE-EMOL 0.05% CREAM	54650						
FLUOCINONIDE 0.1% CREAM	24306						
HALOBETASOL PROP 0.05% CREAM	31251						
HALOBETASOL PROP 0.05% OINTMNT	31211						
HALOG 0.1% CREAM	31441						
HALOG 0.1% OINTMENT	31451						
OLUX 0.05% FOAM	89743						
OLUX-E 0.05% FOAM	97649						
SERNIVO 0.05% SPRAY	40655						
TEMOVATE 0.05% CREAM	32140						
TEMOVATE 0.05% OINTMENT	32130						
TOPICORT 0.05% GEL	06120						
TOPICORT 0.25% CREAM	31181						
TOPICORT 0.25% OINTMENT	30800						
TOPICORT LP 0.05% CREAM	31180						
TOPICORT 0.25% SPRAY	34545						
TRIAMCINOLONE 0.025% CREAM	31231						
TRIAMCINOLONE 0.025% LOTION	31260						
TRIAMCINOLONE 0.025% OINT	31241						
TRIAMCINOLONE 0.1% CREAM	31232						
TRIAMCINOLONE 0.1% LOTION	31261						
TRIAMCINOLONE 0.1% OINTMENT	31242						
TRIAMCINOLONE 0.5% CREAM	31233						
TRIAMCINOLONE 0.5% OINTMENT	31244						
TRIANEX 0.05% OINTMENT	31243						
ULTRAVATE 0.05% CREAM	31251						
VANOS 0.1% CREAM	24306						

	Xolair – IgE-mediated Food Allergy Dosing													
Pretreatment	Dosing						Bod	y Weig	ht (kg	)				
Serum Ige	Frequency	≥10-	>12-	>15-	>20-	>25-	>30-	>40-	>50-	>60-	>70-	>80-	>90-	>125-
(IU/mL)		12	15	20	25	30	40	50	60	70	80	90	125	150
								ose (	mg)					
≥30-100	Every 4	75	75	75	75	75	75	150	150	150	150	150	300	300
>100-200	weeks	75	75	75	150	150	150	300	300	300	300	300	450	600
>200-300		75	75	150	150	150	225	300	300	450	450	450	600	375
>300-400		150	150	150	225	225	300	450	450	450	600	600	450	525
>400-500		150	150	225	225	300	450	450	600	600	375	375	525	600
>500-600		150	150	225	300	300	450	600	600	375	450	450	600	
>600-700		150	150	225	300	225	450	600	375	450	450	525		

>700-800	Every 2	150	150	150	225	225	300	375	450	450	525	600	
>800-900	weeks	150	150	150	225	225	300	375	450	525	600		
>900-1000		150	150	225	225	300	375	450	525	600			
>1000-1100		150	150	225	225	300	375	450	600				
>1100-1200		150	150	225	300	300	450	525	600				
>1200-1300		150	225	225	300	375	450	525					
>1300-1500		150	225	300	300	375	525	600					
>1500-1850			225	300	375	450	600						

	Xolair - Asthma Dosing for Patients 12 years and older								
Pretreatment Serum Ige (IU/mL)	Dosing Frequency	30-60 kg	>60-70kg	>70-90 kg	>90-150 kg				
			Dose	(mg)					
≥30-100	Every 4	150	150	150	300				
>100-200	weeks	300	300	300	225				
>200-300		300	225	225	300				
>300-400	Every 2	225	225	300					
>400-500	weeks	300	300	375					
>500-600		300	375						
>600-700		375							

	Xolair - As	thma	Dosing	for P	atients	s 6 to	< 12	years	of ag	е	
Pretreatment	Dosing	20-	>25-	>30-	>40-	>50-	>60-	>70-	>80-	>90-	>125-
Serum Ige	Frequency	25kg	30kg	40kg	50kg	60kg	70kg	80kg	90kg	125kg	150kg
(IU/mL)											
						Dose	(mg)				
≥30-100	Every 4	75	75	75	150	150	150	150	150	300	300
>100-200	weeks	150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	225	225	225	300	375
>300-400		225	225	300	225	225	225	300	300		
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375				
>600-700		300	225	225	300	375					
>700-800	Every 2	225	225	300	375						
>800-900	weeks	225	225	300	375						
>900-1000		225	300	375							
>1000-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

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Pretreatment	Dosing	>30-	>40-	>50-	>60-	>70-	>80-	>90-	>125-
Serum Ige	Frequency	40kg	50kg	60kg	70kg	80kg	90kg	125kg	150kg
(IU/mL)									
					D	ose (mg)			
≥30-100	Every 4	75	150	150	150	150	150	300	300
>100-200	weeks	150	300	300	300	300	300	450	600
>200-300		225	300	300	450	450	450	600	375
>300-400		300	450	450	450	600	600	450	525
>400-500		450	450	600	600	375	375	525	600
>500-600		450	600	600	375	450	450	600	
>600-700		450	600	375	450	450	525		
>700-800	Every 2	300	375	450	450	525	600		
>800-900	weeks	300	375	450	525	600			
>900-1000		375	450	525	600				
>1000-1100		375	450	600					
>1100-1200		450	525	600					
>1200-1300		450	525						
>1300-1500		525	600						



# **Monoclonal Antibody Agents**

### **Clinical Criteria References**

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- 9. Fasenra (benralizumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
- 10.Nucala (mepolizumab) [prescribing information]. Philadelphia, PA: GlaxoSmithKline LLC; March 2023.
- 11.Tezspire (Tezepelumab-ekko) [prescribing information]. Thousand Oaks, CA: AstraZeneca; May 2023.
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## **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	<ul> <li>Updated Fasenra criteria:         <ul> <li>Updated lookback to 180 days in question #6 on criteria logic and logic diagram</li> <li>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</li> </ul> </li> <li>Updated Nucala criteria:         <ul> <li>Added diagnosis of hypereosinophilic syndrome (HES) and age check to criteria logic and logic diagram</li> <li>Added HES diagnosis table</li> </ul> </li> <li>Updated references</li> </ul>
06/08/2021	<ul> <li>Updated Nucala criteria:</li> <li>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</li> </ul>
08/09/2021	<ul> <li>Updated Nucala criteria:</li> <li>Added diagnosis of chronic rhinosinusitis with nasal polyps for clients ≥ 18 years of age that had an inadequate response to intranasal corticosteroids</li> </ul>
04/27/2022	Combined Dupixent clinical criteria guide with Monoclonal Antibody clinical criteria guide Added criteria for Adbry as approved by the DUR Board
	Added GCN for Dupixent (51385) to PA table Added diagnosis of eosinophilic esophagitis for clients ≥ 12 years of age for Dupixent
06/09/2022	Updated age to ≥ 6 months for Dupixent for patients with atopic dermatitis
06/13/2022	Updated age to ≥ 6 years for Nucala for patients with asthma
07/25/2022	Added criteria for Xolair as approved by the DUR Board on July 22, 2022

Publication Date	Notes
08/10/2022	Added pimecrolimus and tacrolimus (topical) as prior therapy for Dupixent when using to treat atopic dermatitis
10/28/2022	Added diagnosis of prurigo nodularis for clients ≥ 18 years of age for Dupixent Removed ICD-10 codes for unspecified asthma
03/23/2023	Updated Nucala criteria:  Added diagnosis of chronic rhinosinusitis with nasal polyps for clients ≥ 18 years of age that had an inadequate response to intranasal corticosteroids  Updated Dupixent criteria:  Updated age to ≥ 6 months for clients with atopic dermatitis  Removed ICD-10 codes for unspecified asthma  Updated references
01/10/2024	Annual review by staff Added GCNs for AirDuo (48494, 48495, 48489), Armonair (42985, 42979, 48602, 48604, 48615), Asmanex (47599, 37566, 37565), Breyna (98500, 98499), budesonide-formoterol (98500, 98499), fluticasone diskus (53633, 53634, 53635), fluticasone HFA (53639, 53636, 53638), fluticasone-vilanterol (34647, 35808), Ryaltris (49205) Removed GCNs for Beconase AQ (47100) and Nasonex (71431) - products have been discontinued Updated references
01/19/2024	Updated age for Adbry to 12 years and older
02/06/2024	Dupixent – updated age for eosinophilic esophagitis to 1 year and older with weight greater than or equal to 15 kg
03/12/2024	Dupixent – updated step 4 (Is the client $\geq$ 6 years of age?); from 'if no, deny' to 'no, go to step 7'
04/02/2024	Xolair – added diagnosis of IgE-mediated food allergy for clients 1 year and older
05/07/2024	Fasenra – added indication for eosinophilic asthma and updated age to $\geq$ 6 years of age
05/09/2024	Added GCN for Nucala (52416) to Drugs Requiring PA table and to the Duplicate Monoclonal Antibody Therapy table
05/14/2024	Added GCN for Fasenra (55559) to Drugs Requiring PA table and to the Duplicate Monoclonal Antibody Therapy table
08/13/2024	Annual review by staff Updated age for Adbry 150mg/mL syringe to 12 and older Added GCN for Adbry (55922) to drugs requiring PA Added GCN for Airsupra (53534), Beconase AQ (47100), Breztri (48435), and Trelegy Ellipta (43921, 48708) Updated references
09/19/2024	Removed GCN for Fasenra (55559) – product is for healthcare provider administration only

Publication Date	Notes
10/01/2024	Dupixent: Updated age to ≥ 12 years for the diagnosis of chronic rhinosinusitis with nasal polyps and added a diagnosis of COPD for adults  Fasenra: Added a diagnosis of EGPA for adults
11/07/2024	Added criteria for Tezspire
01/07/2025	Added GCNs for Xolair (55222, 55223, 55224, 55225) to Drugs Requiring PA Table
01/31/2025	Added criteria for Ebglyss as approved by the DURB Board