

# Specialty Guideline Management

## Dupixent

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Dupixent	dupilumab

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-approved Indications<sup>1</sup>

- Treatment of patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.
- Add-on maintenance treatment in patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.
- Add-on maintenance treatment in patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).
- Treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).
- Treatment of adult patients with prurigo nodularis (PN).
- Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

- Treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.

#### Limitations of Use

- Not indicated for the relief of acute bronchospasm or status asthmaticus.
- Not indicated for treatment of other forms of urticaria.

### Compendial Uses<sup>25</sup>

- Immune checkpoint inhibitor-related toxicities

All other indications are considered experimental/investigational and not medically necessary.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

### Atopic dermatitis

#### Initial requests

- Chart notes or medical record documentation showing affected area(s) and body surface area (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

#### Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

### Asthma

#### Initial requests

- Chart notes or medical record documentation showing baseline blood eosinophil count (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

#### Continuation requests

Chart notes or medical record documentation supporting improvement in asthma control.

### Chronic rhinosinusitis with nasal polyps (CRSwNP)

## Initial requests

- Chart notes or medical record documentation showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., polyps location, size), or Meltzer Clinical Score or endoscopic nasal polyp score (NPS) (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy.

## Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

## Eosinophilic esophagitis (EoE)

### Initial requests

- Chart notes or medical record documentation showing endoscopic biopsy details including intraepithelial esophageal eosinophil count.
- Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy.

### Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

## Prurigo nodularis (PN)

### Initial requests

- Chart notes or medical record documentation of symptoms (e.g., pruritus, nodular lesions).
- Chart notes, medical record documentation, or claims history supporting previous therapies tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

### Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

## Chronic obstructive pulmonary disease (COPD)

### Initial requests

- Chart notes or medical record documentation demonstrating clinical signs and/or symptoms of COPD.
- Chart notes, medical record documentation, or claims history of prerequisite therapies including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Reference number(s)
1690-A

- Chart notes or medical record documentation showing absolute blood eosinophil count prior to initiating therapy with the requested medication.
- Chart notes or medical record documentation of moderate or severe exacerbations within the last year.

### Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

## Chronic spontaneous urticaria (CSU)

### Initial Requests

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

### Continuation Requests

Chart notes or medical record documentation supporting positive response to therapy.

## Immune checkpoint inhibitor-related toxicities

### Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

## Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Atopic dermatitis: dermatologist or allergist/immunologist
- Asthma: allergist/immunologist or pulmonologist
- Chronic rhinosinusitis with nasal polyps: allergist/immunologist or otolaryngologist
- Eosinophilic esophagitis: gastroenterologist or allergist/immunologist
- Prurigo nodularis: dermatologist or allergist/immunologist
- Chronic obstructive pulmonary disease: pulmonologist or allergist/immunologist
- Chronic spontaneous urticaria: allergist/immunologist or dermatologist
- Immune checkpoint inhibitor-related toxicity: dermatologist, hematologist or oncologist

# Coverage Criteria

## Atopic dermatitis<sup>1-3,7,10,16</sup>

Authorization of 4 months may be granted for members 6 months of age or older who have previously received a biologic (e.g., Adbry, Ebglyss, Nemluvio) or systemic targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past year.

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 6 months of age or older when both of the following criteria are met:

- Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
  - Member has had an inadequate treatment response with one of the following in the past year:
    - A medium potency to super-high potency topical corticosteroid (see Appendix A)
    - A topical calcineurin inhibitor
    - A topical Janus kinase (JAK) inhibitor
    - A topical phosphodiesterase-4 (PDE-4) inhibitor
  - The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age).

## Asthma<sup>1,4-6,11</sup>

Authorization of 6 months may be granted for members 6 years of age or older who have previously received a biologic drug (e.g., Nucala, Cinqair) indicated for asthma in the past year.

Authorization of 6 months may be granted for treatment of moderate-to-severe asthma in members 6 years of age or older when all of the following criteria are met:

- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
  - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
  - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
  - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
- Member meets either of the following criteria:

- Member has a baseline blood eosinophil count of at least 150 cells per microliter and inadequate asthma control despite current treatment with both of the following medications at optimized doses:
  - Medium-to-high-dose inhaled corticosteroid
  - Additional controller (i.e., long-acting beta<sub>2</sub>-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
- Member has inadequate asthma control despite current treatment with all of the following medications at optimized doses (Members should be receiving treatment with inhaled corticosteroid and additional controller for at least the previous 3 months, and oral glucocorticoids for most days during the previous 6 months [e.g., 50% of days, 3 steroid bursts in the previous 6 months]).
  - High-dose inhaled corticosteroid
  - Additional controller (i.e., long-acting beta<sub>2</sub>-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
  - Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent).
- Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

## Chronic rhinosinusitis with nasal polyps (CRSwNP)<sup>1,8,9,12,17,18</sup>

Authorization of 6 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Nucala, Xolair) indicated for CRSwNP in the past year.

Authorization of 6 months may be granted for treatment of CRSwNP in members 12 years of age or older when all of the following criteria are met:

- Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated.
- Member has CRSwNP despite one of the following:
  - Prior sino-nasal surgery
  - Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated
- Member has one of the following:
  - A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril.
  - Meltzer Clinical Score of 2 or higher in both nostrils.
  - A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril.

- Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
  - Rhinorrhea (anterior/posterior)
  - Reduction or loss of smell
  - Facial pain or pressure
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

## Eosinophilic esophagitis (EoE)<sup>1,13-15,27-28,32</sup>

Authorization of 6 months may be granted for treatment of EoE in members 1 year of age or older, weighing at least 15 kg, when all of the following criteria are met:

- Member meets either of the following:
  - Member is 1 year of age to less than 11 years of age and has clinical manifestations of disease (e.g., vomiting, heartburn, abdominal pain, food refusal, failure to thrive).
  - Member is 11 years of age or older and has history of an average of at least 2 episodes of dysphagia (with intake of solids) per week.
- Diagnosis has been confirmed by esophageal biopsy as characterized by 15 or more intraepithelial esophageal eosinophils per high power field.
- Member has had an inadequate treatment response to either of the following:
  - Proton pump inhibitor
  - Swallowed topical corticosteroid therapies (e.g., budesonide, fluticasone [powder or suspension for inhalation]), unless contraindicated or not tolerated

## Prurigo nodularis<sup>19-22</sup>

Authorization of 6 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Nemluvio) indicated for prurigo nodularis in the past year.

Authorization of 6 months may be granted for treatment of prurigo nodularis in members 18 years of age or older when all of the following criteria are met:

- Member has pruritus lasting at least 6 weeks.
- Member has history or signs of repeated itch-scratch cycle (e.g., scratching, picking, or rubbing).
- Member has a minimum of 20 nodular lesions.
- Member meets either of the following:
  - Member has had an inadequate response to one of the following:
    - A medium to super-high potency topical corticosteroid (see Appendix A)
    - A topical calcineurin inhibitor

- Phototherapy (e.g., UVB, PUVA)
- Pharmacologic treatment with methotrexate or cyclosporine
- Member has had an intolerance or a clinical reason to avoid either of the following:
  - Medium to super-high potency topical corticosteroid (see Appendix A) and topical calcineurin inhibitor
  - Pharmacologic treatment with methotrexate and cyclosporine (see Appendix B)

## Chronic obstructive pulmonary disease (COPD)<sup>1,29-31</sup>

Authorization of 12 months may be granted for treatment of COPD in members 18 years of age or older when all of the following criteria are met:

- Diagnosis has been confirmed by spirometry showing forced expiratory volume in one second (FEV<sub>1</sub>)/forced vital capacity (FVC) less than 0.7 post-bronchodilation.
- Member demonstrates classic signs or symptoms of COPD (e.g., dyspnea, wheezing, chest tightness, fatigue, activity limitation, cough with or without sputum production, chronic bronchitis).
- Member has an absolute blood eosinophil count of at least 300 cells per microliter prior to initiating therapy with the requested medication.
- Member has inadequately controlled COPD as demonstrated by experiencing either of the following in the last year:
  - At least two moderate exacerbations resulting in treatment with systemic glucocorticoids, antibiotics, or both.
  - One or more severe exacerbation(s) requiring hospitalization or an emergency medical care visit.
- Member meets either of the following:
  - Member is currently receiving maintenance inhaled triple therapy (i.e., inhaled corticosteroid [ICS], long-acting muscarinic antagonist [LAMA], and long-acting beta<sub>2</sub>-agonist [LABA]).
  - Member is currently receiving a LAMA and LABA, and has a contraindication to ICS.
- Member will continue to use maintenance COPD treatments (e.g., ICS with LAMA and LABA, LAMA and LABA) in combination with the requested medication.

## Chronic spontaneous urticaria (CSU)<sup>1,33-34</sup>

Authorization of 6 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Xolair) indicated for CSU in the past year.

Authorization of 6 months may be granted for treatment of CSU in members 12 years of age or older when all of the following criteria are met:

- Member remains symptomatic despite treatment with up-dosing (in accordance with EAACI/GA2LEN/EuroGuiDerm/APAAACI guidelines) of a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks.



- Member has been evaluated for other causes of wheals (hives) and/or angioedema, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis).
- Member has experienced a spontaneous onset of wheals (hives), angioedema, or both, for at least 6 weeks.

## Immune checkpoint inhibitor-related toxicity<sup>25,26</sup>

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the requested medication will be used for severe (G3) pruritus if no response to gabapentinoids in one month.

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the requested medication will be used as additional therapy for moderate (G2) (e.g., bullous pemphigoid), severe (G3), or life-threatening (G4) bullous dermatitis.

## Continuation of Therapy

### Atopic dermatitis<sup>1-3,10</sup>

Authorization of 12 months may be granted for members 6 months of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis when the member has achieved or maintained a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

### Asthma<sup>1,4-6,11</sup>

Authorization of 12 months may be granted for continuation of treatment of moderate-to-severe asthma in members 6 years of age or older when both of the following criteria are met:

- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
  - A reduction in the frequency or severity of symptoms and exacerbations
  - A reduction in the daily maintenance oral corticosteroid dose
- Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

### Chronic rhinosinusitis with nasal polyps (CRSwNP)<sup>1,8,9,12</sup>

Authorization of 12 months may be granted for continuation of treatment of CRSwNP in members 12 years

of age or older when both of the following are met:

- Member has achieved or maintained a positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sino-nasal inflammation, hyposmia or facial pressure or pain, or reduction in corticosteroid use).
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

## Eosinophilic esophagitis (EoE)<sup>1,13-15</sup>

Authorization of 12 months may be granted for continuation of treatment of EoE in members 1 year of age or older, weighing at least 15 kg, when member has achieved or maintained a positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of EoE (e.g., dysphagia, heartburn, chest pain, emesis).

## Prurigo nodularis<sup>19-22</sup>

Authorization of 12 months may be granted for members 18 years of age or older (including new members) who are using the requested medication for prurigo nodularis when the member has achieved or maintained a positive clinical response as evidenced by either of the following:

- Low disease activity (i.e., clear or almost clear skin)
- Reduction in pruritus intensity and improvement in extent and severity of nodular lesions

## Chronic obstructive pulmonary disease (COPD)<sup>1,29-31</sup>

Authorization of 12 months may be granted for continuation of treatment of COPD in members 18 years of age or older when both of the following criteria are met:

- Member has achieved or maintained a positive clinical response as evidenced by improvement in signs and symptoms of COPD (e.g., decrease in exacerbations, improvement in pre-bronchodilator FEV<sub>1</sub>) or stabilization of disease.
- Member will continue to use maintenance COPD treatments (e.g., ICS with LAMA and LABA, LAMA and LABA) in combination with the requested medication.

## Chronic spontaneous urticaria (CSU)<sup>1,33-34</sup>

Authorization of 12 months may be granted for continuation of treatment of chronic spontaneous urticaria in members 12 years of age or older, when the member has experienced a positive clinical response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy.

## Immune checkpoint inhibitor-related toxicities<sup>25</sup>

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immune checkpoint inhibitor-related severe (G3) pruritus or moderate (G2) (e.g., bullous pemphigoid), severe (G3), or life-threatening (G4) bullous dermatitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

## Other

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

## Appendix

### Appendix A: Table. Relative potency of select topical corticosteroid products<sup>7</sup>

Potency	Drug	Dosage form	Strength
I. Super-high potency (Group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (Group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (Group 1)	Fluocinonide	Cream	0.1%
I. Super-high potency (Group 1)	Flurandrenolide	Tape	4 mcg/cm <sup>2</sup>
I. Super-high potency (Group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (Group 2)	Amcinonide	Ointment	0.1%
II. High potency (Group 2)	Augmented betamethasone dipropionate	Cream	0.05%

Potency	Drug	Dosage form	Strength
II. High potency (Group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (Group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (Group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (Group 2)	Desoximetasone	Gel	0.05%
II. High potency (Group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (Group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (Group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (Group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (Group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (Group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (Group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (Group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (Group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (Group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (Group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (Group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (Group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (Group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (Group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (Group 4)	Clocortolone pivalate	Cream	0.1%

Potency	Drug	Dosage form	Strength
IV. Medium potency (Group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (Group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (Group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (Group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (Group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (Group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (Group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (Group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (Group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (Group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (Group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (Group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (Group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (Group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (Group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (Group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (Group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (Group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (Group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (Group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%

Potency	Drug	Dosage form	Strength
VI. Low potency (Group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (Group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (Group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (Group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (Group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (Group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (Group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (Group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (Group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (Group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (Group 7)	Hydrocortisone acetate	Cream	1%

## Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate or Cyclosporine<sup>23,24</sup>

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

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