Urticaria Measure #1: Overuse: Laboratory Tests for Connective Tissue Disease

Measure Description
Percentage of patients seen at one or more visits within a 12-month period with a diagnosis of chronic urticaria/angioedema, who underwent diagnostic testing for connective tissue disease in the absence of a history or symptoms consistent with or suggestive of a connective tissue disease.

Measure Components:

Numerator Statement
Number of patient who underwent diagnostic evaluation that included obtaining serologic testing for autoimmune disorders (e.g., ANA, Anti-SSA, Anti-SSB, dsDNA, Anti-Scl 70).

Denominator Statement
Total number of new patients with a diagnosis of chronic urticaria/angioedema without symptoms suggestive for connective tissue disease – including but not limited to: photosensitivity, oral ulcers, xerophthalmia, pleuritis/pericarditis, joint tenderness, swelling, or effusion

Denominator Exceptions
Exclusions – patients with chronic urticaria/angioedema and concomitant or suspected auto-immune disorder (e.g, SLE, Sjogren's, Scleroderma, etc.).

Supporting Guideline & Other References
The following evidence statements are quoted verbatim from the referenced clinical guidelines:

SUMMARY STATEMENT 15: Serology to diagnose underlying autoimmune diseases (e.g., connective tissue disease) is not warranted in the initial evaluation of CHRONIC URTICARIA.

Reference- Bernstein J, et al. The Diagnosis and Management of Acute and Chronic Urticaria: 2014 Update, Journal of Allergyand Clinical Immunology 2014 – submitted.

Measure Importance

Relationship to desired outcome -- The underlying cause of chronic urticaria is usually idiopathic. Cases of chronic idiopathic urticaria (CIU) include 30% to 60% with an autoimmune phenotype. There are no convincing data that demonstrate such evidence of autoimmunity is pathophysiologic for the development of urticaria. For this reason, workup for other autoimmune disorders is inappropriate in the vast majority of patients with chronic urticaria. ***However, as connective tissue disease and other autoimmune disorders may occasionally present in an atypical manner that are yet to be validated in prospective studies, consensus by the AAAAI and ACAAI Joint Task Force on Quality Measures has determined that an error rate of no more than 25% is acceptable for this measure to allow for clinician discretion to evaluate atypical cases.***

IOM Domains of Health Care Quality Addressed
- Efficient
- Cost effective

Exception Justification -- The Chronic Urticaria Work Group agreed to include medical reason(s) for working up patients with CHRONIC URTICARIA and concomitant auto-immune disorder (e.g, SLE, Sjogren's, Scleroderma, etc.) and patients whose presentation entails atypical features of history, physical

exam, and/or laboratory studies including biopsy c/w leukocytoclastic vasculitis, for whom ordering serologic testing is appropriate.

Harmonization with Existing Measures -- Harmonization with existing measures was not applicable to this measure.

Measure Designation

Measure Purpose
- Maintenance of Certification® Programs
- Quality improvement

Type of Measure
- Process

Level of Measurement
- Physician
- Provider Group
- Other healthcare professional

Care Setting
- Ambulatory care
- Inpatient care

Possible Data Source
- Electronic administrative data/claims
- Electronic health/medical record
- Registry data

Urticaria Measure #2: Overuse: Laboratory Tests for Food Allergy

Measure Description
Percentage of patients seen at one or more visits within a 12-month period with a diagnosis of chronic urticaria/angioedema, who underwent skin or in vitro testing for food allergies.

Measure Components:

Numerator Statement
Number of patients who underwent diagnostic evaluation that included skin or in vitro testing for food allergies.

Denominator Statement
Total number of patients with a diagnosis of chronic urticaria/angioedema in the past 12 months.

Denominator Exceptions
Exclusions:

1. Patients with chronic urticaria who also have a history compatible with allergy to food(s), or who may have a condition exacerbated by food(s), e.g., exercise-induced anaphylaxis or eosinophilic esophagitis.
2. Patients with exercise-induced urticaria/anaphylaxis, which may be food-associated.

Supporting Guideline & Other References
The following evidence statements are quoted verbatim from the referenced clinical guidelines:

SUMMARY STATEMENT 29: After a thorough history and physical examination, no diagnostic testing may be appropriate for some patients with CU; however, limited routine lab testing may be performed to exclude underlying causes (E). Targeted lab testing based on clinical suspicion is appropriate. Extensive routine testing for exogenous and rare causes of CU, or immediate hypersensitivity skin testing for inhalants or foods, is not warranted. Routine laboratory testing in patients with CU, whose history and physical examination lacks atypical features, rarely yields clinically significant findings.

SUMMARY STATEMENT 35: Immediate hypersensitivity skin or serologic testing for food or other allergens is rarely useful, and therefore not indicated on a routine basis. [D]

Reference- Bernstein J, et al. The Diagnosis and Management of Acute and Chronic Urticaria: 2014 Update, Journal of Allergy and Clinical Immunology 2014 – submitted.

Measure Importance

Relationship to desired outcome -- As the underlying cause of chronic urticaria is usually idiopathic, without classic signs or symptoms of a food allergy, the work-up of chronic urticaria should not routinely include testing for food allergies. However, as there may be a small subset of urticaria/angioedema that is caused by food allergies without classic signs or symptoms, consensus by the AAAAI and ACAAI Joint Task Force on Quality Measures has determined that an error rate of no more than 10% is acceptable for this measure to allow for clinician discretion to evaluate atypical cases.

Opportunity for Improvement

IOM Domains of Health Care Quality Addressed

- Efficient
- Cost effective

Exception Justification -- The Chronic Urticaria Work Group agreed to include limited food testing to specific food that patient may suspect. The group discourages the use of food in fixed panels that require treating of all foods in that panel without a history of IgE mediated potential to that select food. (Note inhalant is another measure)

Harmonization with Existing Measures -- Harmonization with existing measures was not applicable to this measure.

Measure Designation

Measure Purpose
- Maintenance of Certification® Programs
- Quality improvement

Type of Measure
- Process

Level of Measurement
- Physician
- Provider Group
- Other healthcare professional

Care Setting
- Ambulatory care
- Inpatient care

Possible Data Source
- Electronic administrative data/claims
- Electronic health/medical record
- Registry data

Urticaria Measure #3: Overuse: Laboratory Tests for Inhalant Allergy

Measure Description
Percentage of patients seen at one or more visits within a 12-month period with a diagnosis of chronic urticaria/angioedema, who underwent skin or in vitro testing for inhalant allergens.

Measure Components:

Numerator Statement
Number of patients who underwent diagnostic evaluation that included skin or in vitro testing for inhalant allergens.

Denominator Statement
Total number of patients with a primary diagnosis of chronic urticaria/angioedema in the past 12 months.

Denominator Exceptions
Exclusions: Patients with chronic urticaria and concomitant chronic rhinitis, rhino- sinusitis, chronic conjunctivitis, asthma, and/or atopic dermatitis for whom further diagnostic evaluation with immediate hypersensitivity skin testing or serum specific IgE testing to inhalants is appropriate.

Supporting Guideline & Other References
The following evidence statements are quoted verbatim from the referenced clinical guidelines:

SUMMARY STATEMENT 29: After a thorough history and physical examination, no diagnostic testing may be appropriate for some patients with CU; however, limited routine lab testing may be performed to exclude underlying causes (E). Targeted lab testing based on clinical suspicion is appropriate. Extensive routine testing for exogenous and rare causes of CU, or immediate hypersensitivity skin testing for inhalants or foods, is not warranted. Routine laboratory testing in patients with CU, whose history and physical examination lacks atypical features, rarely yields clinically significant findings.

SUMMARY STATEMENT 35: Immediate hypersensitivity skin or serologic testing for food or other allergens is rarely useful, and therefore not indicated on a routine basis. [D]

Reference- Bernstein J, et al. The Diagnosis and Management of Acute and Chronic Urticaria: 2014 Update, Journal of Allergy and Clinical Immunology 2014 – submitted.
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Measure Importance

Relationship to desired outcome -- As the underlying cause of chronic urticaria is usually idiopathic, without classic signs or symptoms of an inhalant allergy, the work-up of chronic urticaria should not routinely include testing for inhalant allergies. However, as there may be a small subset of urticaria/angioedema that is caused by inhalant allergies without classic signs or symptoms, consensus by the AAAAI and ACAAI Joint Task Force on Quality Measures has determined that an error rate of no more than 10% is acceptable for this measure to allow for clinician discretion to evaluate atypical cases.

Opportunity for Improvement

IOM Domains of Health Care Quality Addressed
- Efficient
- Cost effective

Exception Justification -- The Chronic Urticaria Work Group agreed to include limited inhalant testing in patients with allergic rhinitis, allergic conjunctivitis or allergic asthma.

Harmonization with Existing Measures -- Harmonization with existing measures was not applicable to this measure.

Measure Designation

Measure Purpose
- Maintenance of Certification® Programs
- Quality improvement

Type of Measure
- Process

Level of Measurement
- Physician
- Provider Group
- Other healthcare professional

Care Setting
- Ambulatory care
- Inpatient care

Possible Data Source
- Electronic administrative data/claims
- Electronic health/medical record
- Registry data

Urticaria Measure #4: Overuse: Laboratory Tests for Hereditary or Acquired Angioedema

Measure Description
Percentage of patients seen at one or more visits within a 12-month period with a diagnosis of chronic urticaria with or without angioedema, who underwent diagnostic testing for a C1 inhibitor deficiency syndrome.

Measure Components:

Numerator Statement
Number of patients who underwent diagnostic evaluation that included a C1 esterase Inhibitor level and/or functional assay.

Denominator Statement
Total number of patients with a diagnosis of acute or chronic urticaria with or without angioedema

Denominator Exceptions
Exclusion: patients presenting with angioedema without urticaria

Supporting Guideline & Other References
The following evidence statements are quoted verbatim from the referenced clinical guidelines:

SUMMARY STATEMENT 29: After a thorough history and physical examination, no diagnostic testing may be appropriate for some patients with CU; however, limited routine lab testing may be performed to exclude underlying causes (E). Targeted lab testing based on clinical suspicion is appropriate. Extensive routine testing for exogenous and **rare causes of CU**, or immediate hypersensitivity skin testing for inhalants or foods, is not warranted. Routine laboratory testing in patients with CU, whose history and physical examination lacks atypical features, rarely yields clinically significant findings.

Reference: Bernstein J, et al. The Diagnosis and Management of Acute and Chronic Urticaria: 2014 Update, Journal of Allergy and Clinical Immunology 2014 – submitted.

A history of angioedema alone may suggest a rare disorder of C1esterase inhibitor deficiency, which may be inherited as an autosomal dominant or acquired angioedema due to C1esterase inhibitor deficiency may present as an acute episode of regional swelling following trauma (eg, dental manipulation of the oropharynx) or episodic abdominal pain which is thought to be secondary to angioedema involving the intestinal tract. Although C1 esterase inhibitor deficiency may present as an acute episode, detailed history may confirm the recurrent nature of these disorders. It is advised that **screening C4 levels be obtained on all patients with chronic angioedema without urticaria**, especially patients with the aforementioned history

Reference: Zuraw B,et al. A Focused Parameter Update: Hereditary Angioedema, Acquired C1 Inhibitor Deficiency, and ACE-Inhibitor Associated Angioedema. J Allergy Clin Immunol; 2013, 131: 1491-3.

Approximately 40% of patients also have angioedema (swelling of the subdermis) that accompanies the urticarial lesions. In a smaller number, approximately 10%, angioedema is present without visible urticaria.

Reference: Powell RJ, Du Toit GL, Siddique N, Leech SC, Dixon TA, Clark AT, et al. BSACI guidelines for the management of chronic urticaria and angio-edema. Clin Exp Allergy 2007;37:631-50.

Measure Importance

Relationship to desired outcome -- While many patients with chronic urticaria have concomitant angioedema, only 10% present with angioedema alone. Hereditary and acquired angioedema do not classically present with urticaria, thus obtaining laboratory studies to rule out C1 inhibitor deficiency is not warranted in the overwhelming proportion of patients who have urticaria alone or urticaria in combination with angioedema. However, as atypical cases may rarely occur, consensus by the AAAAI and ACAAI Joint Task Force on Quality Measures has determined that an error rate of no more than 10% is acceptable for this measure to allow for clinician discretion to evaluate atypical cases.

Opportunity for Improvement -- Use of appropriate laboratory tests

IOM Domains of Health Care Quality Addressed
- Efficient
- Cost effective

Exception Justification -- The Chronic Urticaria Work Group agreed to include chronic urticaria, which may initially present with angioedema alone.

Harmonization with Existing Measures -- Harmonization with existing measures was not applicable to this measure.

Measure Designation

Measure Purpose
- Maintenance of Certification® Programs
- Quality improvement

Type of Measure
- Process

Level of Measurement
- Physician
- Provider Group
- Other healthcare professional

Care Setting
- Ambulatory care
- Inpatient care

Possible Data Source
- Electronic administrative data/claims
- Electronic health/medical record
- Registry data

Urticaria Measure #5: Underuse: Higher doses of Antihistamines

Measure Description
The proportion of patients with chronic urticaria that is uncontrolled on monotherapy with approved doses of 2nd generation antihistamines, who are advanced as tolerated to one or more of the following: higher doses of second generation antihistamines; addition of another 2nd generation antihistamine, addition of a leukotriene antagonist, addition of an H2 blocker, or addition of a 1st generation antihistamine to be taken at bedtime.

Measure Components:

Numerator Statement
Number of patients for whom one or more of the following has been prescribed: higher doses of second generation antihistamines; addition of another 2nd generation antihistamine, addition of an H2 blocker, addition of a leukotriene antagonist; addition of 1st generation antihistamine to be taken at bedtime.

Denominator Statement
Number of patients seen in the past 12 months with a diagnosis of chronic urticaria/angioedema whose disease is uncontrolled on monotherapy with approved doses of 2nd generation antihistamine.

Denominator Exceptions

Patients, who after counseling from the physician, refuse the above therapies.

Clarification: Some patients may be intolerant of or at elevated risk for adverse reactions from higher doses of sedating antihistamines. Examples include but are not limited to: older adults who at greater risk for untoward consequences of anticholinergic effects, certain occupations -- such as pilots or police officers, for whom drowsiness or performance impairment must be avoided. These patients would still be candidates for trials of another non-sedating antihistamine, an H2 antihistamine, and/or an anti-leukotriene drug.

Supporting Guideline & Other References
The following evidence statements are quoted verbatim from the referenced clinical guidelines:

SUMMARY STATEMENT 82: Higher doses of second-generation antihistamines may provide more efficacy. (B)

SUMMARY STATEMENT 83: First generation antihistamines may be considered in patients failing higher dose second generation antihistamines. (D)

SUMMARY STATEMENT 84: H2-antagonists have been shown to be effective in combination with first and second-generation antihistamines compared to antihistamines alone for the treatment of CU. (A) However, this benefit may be related to pharmacologic interactions and increased blood levels of first generation antihistamines. (B) Addition of H2-antagonists may be considered when CU is not optimally controlled with second generation antihistamine monotherapy. (D)

SUMMARY STATEMENT 85: Several randomized controlled studies have shown efficacy of leukotriene receptor antagonists in CU. (A) Leukotriene receptor antagonists are generally well tolerated (A). Leukotriene receptor antagonists may be considered for CU patients with unsatisfactory responses to H-2 antihistamine monotherapy.

Reference: Bernstein J, et al. The Diagnosis and Management of Acute and Chronic Urticaria: 2014 Update, Journal of Allergy and Clinical Immunology 2014 – submitted

Measure Importance

Relationship to desired outcome -- Patients with uncontrolled chronic urticaria/angioedema may benefit from H1 antihistamine medication or a administered at higher than conventional doses, with or without concomitant H2-antihistamine and/or anti-leukotriene agent.

IOM Domains of Health Care Quality Addressed

- Safety
- Cost effective

Exception Justification -- The Chronic Urticaria Work Group realize that some patients are intolerant to these first line therapies, and acknowledges that compliance with this measure may entail off-label prescribing and/or dosing. As is the case in a number of therapeutic areas, although the FDA has not approved combination therapy and antihistamine dose advancement as encouraged in this measure, there are data in the medical literature that support this recommendation and lead to a strong recommendation based on evidence this will lead to improved patient care outcomes. ‘