

- Aims:**
1. Assess the likelihood a patient has a true penicillin allergy empirically or by testing
 2. Delabel patients who have been incorrectly labeled as penicillin-allergic

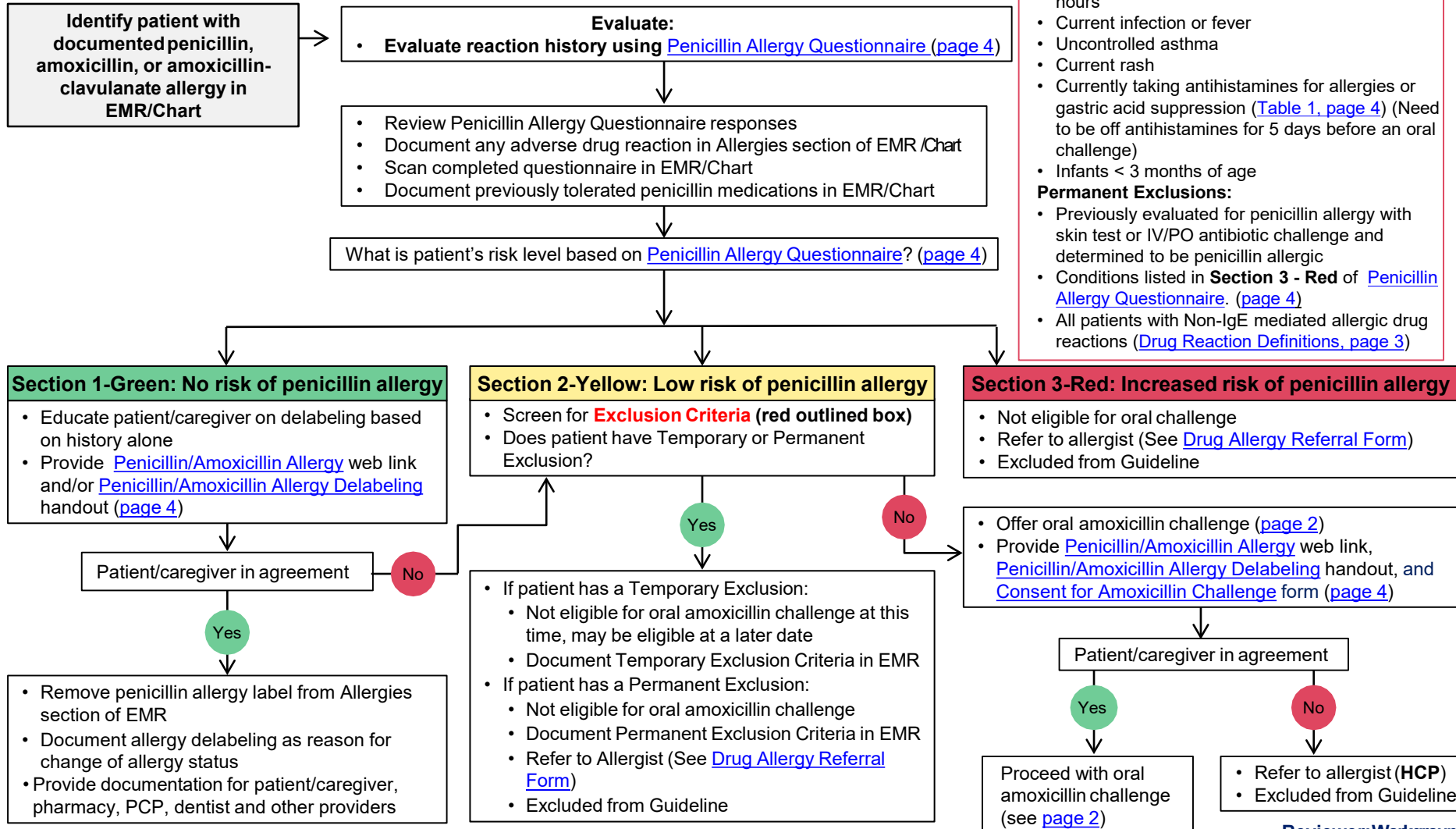
EXCLUSION CRITERIA: Patients excluded from oral amoxicillin challenge

Temporary Exclusions:

- Critically ill, NPO, or vomiting >1 time in last 24 hours
- Current infection or fever
- Uncontrolled asthma
- Current rash
- Currently taking antihistamines for allergies or gastric acid suppression ([Table 1, page 4](#)) (Need to be off antihistamines for 5 days before an oral challenge)
- Infants < 3 months of age

Permanent Exclusions:

- Previously evaluated for penicillin allergy with skin test or IV/PO antibiotic challenge and determined to be penicillin allergic
- Conditions listed in **Section 3 - Red** of [Penicillin Allergy Questionnaire](#). ([page 4](#))
- All patients with Non-IgE mediated allergic drug reactions ([Drug Reaction Definitions, page 3](#))



- Aims:**
1. Develop a systematic approach to identify patients with a penicillin allergy label
 2. Assess the likelihood a patient has a true penicillin allergy empirically or by testing
 3. Delabel patients who have been incorrectly labeled as penicillin-allergic

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Off guideline ← No — Patient eligible for amoxicillin oral challenge

Yes

Oral challenge only performed when the following criteria are met:

- Parent/guardian is present and able to stay in clinic for at least 60 minutes
- Signed Consent form
- Adequate staffing to support oral challenge
- A provider aware of timing of oral challenge
- Rescue medications are immediately available for administration if needed

Reschedule for when criteria can be met ← No

Yes

- Educate patient/caregiver about signs/symptoms of allergic reaction to watch for and to notify the nurse immediately if there are symptoms. ([Drug Reaction Definitions, page 3](#))
- Obtain baseline vital signs (BP, HR, O2, resp rate, temp, pain) and perform baseline assessment.
- Give oral amoxicillin dose (45 mg/kg, max 1000 mg) once.
- Stay with patient and observe for signs/symptoms of allergic reaction for first 15 min. Reassess patient and obtain vital signs at 15 min after dose.
- Remind patient/caregiver to notify staff immediately if experiencing any symptoms or change in how patient is feeling.
- Reassess patient and obtain vital signs at 60 min after dose.

← No

- Remove penicillin allergy label from Allergies section of EMR
- Document "Patient passed oral amoxicillin challenge [date, time]"
- Provide documentation for patient/caregiver, pharmacy, and other providers (e.g. PCP, dentist, etc.)

Positive Reaction?
Any reaction at any time during the oral amoxicillin challenge as defined in:
2. [Allergic Drug Reactions \(page 3\)](#) or
3. [Anaphylaxis \(page 3\)](#)

Yes →

- Manage per [Treatment of Positive Oral Challenge Test Reactions](#) document
- Do not remove allergy label from EMR.
- Document specific reaction(s) in Allergies section of EMR
- Document patient did NOT pass oral amoxicillin challenge in EMR
- Consider referral to allergist for further assessment if test was inconclusive

Drug Reaction Definitions: Non-Allergic vs Allergic

1. Non-Allergic Adverse Drug Reactions - Signs/Symptoms/Reactions that are doubtful for presence of penicillin drug allergy: (and/or unlikely to require further assessment by an allergist)

- | | |
|--|--|
| <ul style="list-style-type: none"> a. headache b. diarrhea c. nausea d. single episode of vomiting | <ul style="list-style-type: none"> e. transient pruritus without rash f. mild self-limited rash (not hives) g. persistent rhinorrhea (≥ 3 min) h. persistent rubbing of nose or eyes (≥ 3 min) |
|--|--|

2. Allergic Drug Reactions - Signs/Symptoms/Reactions consistent with a penicillin drug allergy by organ system:

- | | |
|---|---|
| <ul style="list-style-type: none"> a. Skin: Urticaria (hives), flushing, exanthem, angioedema, mouth or eye soreness, persistent pruritus (≥ 3 min) b. Cardiovascular: Hypotension, syncope (see below) c. Gastrointestinal: Repetitive vomiting, abdominal cramping | <ul style="list-style-type: none"> d. Musculoskeletal: Hypotonia e. Respiratory: Dyspnea, wheezing, hypoxia, repetitive coughing, stridor, vocal changes (dysphonia, aphonia) |
|---|---|

3. Anaphylaxis - More severe allergic reaction is highly likely if one of the following 2 criteria are met (See [Anaphylaxis Guideline](#)):

- a. Acute onset* of changes to skin, mucosal tissue, or both (e.g. generalized hives, pruritus or flushing, swollen lips-tongue-uvula) AND ≥1 of the following:
 - i. Respiratory compromise (e.g. dyspnea, wheeze-bronchospasm, coughing, stridor, throat tightness, hoarse voice, reduced peak respiratory flow (PEF), hypoxemia)
 - ii. Hypotension/reduced blood pressure** or associated symptoms of end-organ dysfunction (e.g. pale, blue, faint, weak pulse, dizzy, confused, hypotonia [collapse], syncope, incontinence)
 - iii. Severe gastrointestinal symptoms (e.g. severe crampy abdominal pain, repetitive vomiting, severe diarrhea)
- b. Acute onset of hypotension** or bronchospasm or laryngeal involvement (stridor, vocal changes, odynophagia) even in the absence of typical skin involvement

*Minutes to several hours from exposure. Most immediate reactions occur within the 1st hour following drug administration.

**Hypotension defined as systolic blood pressure (mm Hg):

< 12 months of age: < 70

1-10 years of age: <70 + (2 × age in years)

> 10 years of age: < 90

4. Non-IgE mediated allergic drug reactions:

- | | |
|---|---|
| <ul style="list-style-type: none"> a. Drug-induced neutrophilic dermatosis (Sweet's syndrome) b. Drug-induced autoimmune diseases (bullous pemphigoid, pemphigus vulgaris, linear IgA bullous dermatosis, drug-induced lupus) c. Organ-specific drug-induced liver injury, nephritis, pneumonitis, meningitis, pancreatitis or cytopenias) d. Drug-induced vasculitis (leukocytoclastic vasculitis, eosinophilic granulomatosis with polyangiitis) e. Serum sickness or Serum sickness like reaction | <ul style="list-style-type: none"> f. Stevens-Johnson syndrome (SJS). g. Toxic epidermal necrolysis (TEN). h. Drug reaction with eosinophilia and systemic symptoms (DRESS). i. Acute generalized exanthematous pustulosis (AGEP). j. Generalized bullous fixed drug eruption (GBFDE). k. Severe† maculopapular rash. l. Blood disorders (hemolytic anemia, agranulocytosis, thrombocytopenia). m. Drug fever |
|---|---|

Table 1. Patients are excluded if they received any of the following antihistamines within the specified timeframe prior to the anticipated oral amoxicillin challenge.

Azelastine Nasal Spray (Astelin™, Astepro™)		12 days
Cetirizine (Zyrtec™)	Hydroxyzine (Atarax™)	5 days
Chlorpheniramine (Chlortimeton™)	Levocetirizine (Xyzal™)	
Desloratadine (Clarinet™)	Loratadine (Claritin™)	
Diphenhydramine (Benadryl™)	Promethazine (Phenergan™)	
Fexofenadine (Allegra™)	Over the counter cold & cough medications	
Cimetidine (Tagamet™)	Ketotifen Eye Drops (Alaway™, Eye Itch Relief™, Zaditor™)	2 days
Famotidine (Pepcid™)	Olopatadine Nasal Spray or Eye Drops (Patanase™, Patanol™, Pazeo™)	
Nizatidine (Axid™)		

Penicillin Allergy Delabeling patient/caregiver materials based on primary language

Please contact CHN or see original Guideline distribution email for Somali and Spanish questionnaire and consent form.

Patient's Preferred Language	Penicillin Allergy Delabeling Materials
English	Questionnaire, Patient/Caregiver Education, Consent Form
Hmong	Patient/Caregiver Education
Somali	Questionnaire, Patient/Caregiver Education, Consent Form
Spanish	Questionnaire, Patient/Caregiver Education, Consent Form

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Resource

<https://education.aaaai.org/penicillin-allergy-center/penicillin>

Workgroup: Bies, Chase, Hollerud, Inman, Ohnstad, Pomputius, Schmit, Ullman

Allergist - Drug Allergy Referral Communication Form

To fill in or use clinic sticker here

PCP: _____
Clinic name: _____
Clinic address: _____
Phone #: _____ Fax #: _____

Referral date: _____ Patient address: _____
Patient name: _____ City: _____ State: _____ Zip: _____
DOB: _____ Parent/Guardian: _____
Preferred Phone: _____ Alternate Phone: _____

Allergist Consult request for:

- Allergist to evaluate and recommend treatment options
- Patient/parent requested a consult with Allergist to discuss treatment options
- Other clinical concern: _____

Reason for Referral (check all that apply):

- Penicillin Allergy**
 - Failed oral amoxicillin challenge
 - High risk category on screening questionnaire; oral challenge not performed
 - Other concern: _____
- Other Drug(s) Allergy-** _____
 - Failed oral drug challenge
 - Other concern

Clinical Concerns/Red Flags (check all that apply)

- Asthma history
- Type I reactions - hives, angioedema, swelling of lips, tongue, bronchospasm, hypotension, anaphylaxis
- Type II reactions - hemolytic anemia, thrombocytopenia
- Type III reactions - fever, serum sickness, vasculitis, arthralgia, erythema multiforme
- Type IV reactions - Stevens Johnson, DRESS, TENS, etc.
- Other: _____

Include all relevant records and any comments (check documents that are included)

- Recent relevant encounter notes
- Skin prick or intradermal test results
- Oral penicillin/amoxicillin challenge test results
- Other relevant lab results: _____

Additional comments:

Primary Care Clinician Signature: _____ **Date:** _____

Fax completed form and other documents to Allergy Group - see list of providers in Guideline

Amoxicillin Liquid Oral Challenge Dosing Directions

Amoxicillin 400 mg/5ml (80 mg/ml)

For a 45 mg/kg dose:

- Prepare the Amoxicillin 400mg/5ml as normal (per package insert).
- Remove 0.56 ml (=45mg) of the suspension per kg of body weight.
 - 5 kg = 2.8 ml
 - 10 kg = 5.6 ml
 - 15 kg = 8.4 ml
 - 20 kg = 11.3 ml
 - 22.2 kg = 12.5 ml (max 1000 mg dose)

Amoxicillin 250 mg/5ml (50 mg/ml)

For a 45 mg/kg dose:

- Prepare the Amoxicillin 250mg/5ml as normal (per package insert).
- Remove 0.9 ml (=45mg) of the suspension per kg of body weight.
 - 5 kg = 4.5 ml
 - 10 kg = 9.0 ml
 - 15 kg = 13.5 ml
 - 20 kg = 18 ml
 - 22.2 kg = 20 ml (max 1000 mg dose)

Amoxicillin 200 mg/5ml (40 mg/ml)

For a 45 mg/kg dose:

- Prepare the Amoxicillin 200mg/5ml as normal (per package insert).
- Remove 1.125 ml (=45mg) of the suspension per kg of body weight.
 - 5 kg = 5.6 ml
 - 10 kg = 11.25 ml
 - 15 kg = 16.9 ml
 - 20 kg = 22.5 ml
 - 22.2 kg = 25.0 ml (max 1000 mg dose)

*CHN recommends single day use of liquid reconstituted amoxicillin products. However, reconstituted amoxicillin can be stored for up to 7-days if refrigerated. Reconstituted amoxicillin products should be labeled with the concentration, date of reconstitution and expiration date.

Penicillin Allergy Delabeling Guideline

Treatment for Positive Oral Challenge Test Reactions

Minor reactions - pruritis, mild skin rash, mild hives

- Antihistamine:
 - Cetirizine (Zyrtec): 5 mg/5 ml, 2.5 mg chewable, 10 mg chewable, 5 mg tablet, 10 mg tablet/dissolve tab/liquid gels
 - < 2 years - 2.5 mg
 - 2-5 years – 5 mg
 - > 6 years – 10 mg
 - Diphenhydramine (Benadryl): 12.5 mg/5 ml, 12.5 mg chewable, 25 mg tablet/liqui-gels, 50 mg tablet
 - 25 lbs. - 12.5 mg
 - 37.5 lbs. - 18.75 mg
 - 50 lbs. - 25 mg
 - 75 lbs. - 37.5 mg > 100 lbs. - 50 mg
- Observe for an additional 60 minutes or more to watch for additional symptoms

Major reactions - diffuse hives, wheezing, coughing, tightness in throat, trouble swallowing, difficulty breathing, pale, faint, dizzy, repeated vomiting, etc. Treatment based on symptoms exhibited

- Epinephrine - for all types of major reactions
 - Epinephrine Auto injector:
 - < 55 lbs. - 0.15mg
 - > 55 lbs. - 0.3mg
 - Nasal Epinephrine (Neffy) > 4 years
 - 33-66 lbs. - 1 mg - 1 spray
 - > 66 lbs. - 2 mg - 1 spray
 - Give 2nd dose of epinephrine about 5 minutes after 1st dose if symptoms return or do not improve
- Bronchodilator - for major reactions that include wheezing, coughing, or trouble breathing
 - Albuterol
 - Nebulize 1 vial nebulized
 - MDI - 2-4 puffs with spacer device
- Stay with patient continuously and observe for an additional 60 minutes or more until symptoms have resolved
- Call 911 if not responding to treatment

Clinic Visit Note: Amoxicillin Challenge

Chief Complaint:

Patient Name presents for oral amoxicillin drug challenge

HPI:

Patient Name has a history of penicillin allergy documented in EMR/Chart.

Penicillin Allergy Questionnaire screening placed the patient in a low-risk category and is eligible for oral amoxicillin challenge.

Review of Systems:

Negative for recent fever, rhinorrhea, rash, cough, wheezing, vomiting, diarrhea.

Baseline Vital Signs:

HR:

Resp:

B/P:

Temp:

Exam: (default limit normal exam template, focus on ENT, Chest, Heart and Skin exam)

Challenge procedure details:

- Single dose of amoxicillin (45 mg/kg, max 1000 mg) given orally

Emergency medications readily available and physician directly available in office throughout the duration of challenge for treatment of allergic reaction.

Assessment/Plan:

#Negative Challenge

- The patient tolerated amoxicillin challenge today without immediate reaction. Greater than 61 minutes was spent performing the amoxicillin challenge. Removed penicillin allergy label from the patient's chart and counseled patient/family to avoid mentioning allergy to penicillin at future health care visits.
- Although very low on the risk, there's a possibility of delayed reactions, including itchy rash. If this arises, recommend family administer oral antihistamine and contact our office.
- Use Dx Code:
 - Z88.0 - *Allergy status to penicillin*

OR

#Positive Challenge

- The patient was unable to tolerate the amoxicillin challenge today. The patient was treated with *** and observed in our clinic setting for *** minutes. There were no further symptoms noted and the family and patient were instructed to continue avoidance of ***. For tests with equivocal results, will refer to allergy for further evaluation.
- Use Dx Codes:
 - Z88.0 - *Allergy status to penicillin*
 - L27.0 - *Generalized skin eruption due to drugs and medicaments taken internally*
 - Use this code or another code that describes the particular reaction
 - T36.0X5A - *Adverse effect of penicillin, initial encounter*

Penicillin Allergy Delabeling Guideline

Protocol for Oral Amoxicillin Allergy Challenge in Children in Outpatient Setting

Prior to challenge

- Educate involved staff regarding purpose of challenges, benefits, and low risks.
- Normal staffing ratios are acceptable and 1:1 staffing is not needed (same level of staffing as for routine vaccinations)
- Need area to administer doses and a room (or waiting room) for monitoring
- Medications needed:
 - Amoxicillin in liquid or capsule form
 - Oral antihistamine (e.g. cetirizine or diphenhydramine), liquid and pill forms
 - Epinephrine:
 - epinephrine autoinjector - 0.15mg & 0.3mg
 - nasal epinephrine - 1 mg & 2 mg
 - NOT 1:10000 epinephrine ampules in crash cart
 - Albuterol (MDI and/or neb)
- Obtain verbal or written consent from patient - Consent for Amoxicillin Challenge
- Patients should stay on other medications, should NOT go through challenge if on other antibiotics or antihistamines

Challenge appointment

- Obtain vital signs
- Physical exam with close attention to cutaneous findings
- 1-step amoxicillin challenge
 - Single dose 45 mg/kg, max 1000 mg
- Post challenge wait time: 60 minutes minimum, longer for patients with allergic reactions

Post-challenge education

- Document penicillin allergy status in EMR
 - Negative challenge - remove penicillin allergy label in EMR/Chart and document negative oral challenge
 - Positive challenge - keep penicillin allergy in EMR/Chart and document oral challenge reaction
- Inform other physicians regarding the appointment
- Negative Oral Challenge:
 - Advise caregivers to ask to have penicillin allergy removed from EMRs that don't communicate with local EMR
 - Consider notifying patient's pharmacy, dentist, school nurse, etc.
 - Advise patient / caregivers to NOT mention penicillin allergy at future medical appointments
- Advise patient / caregivers to contact office with any new rash or other symptoms
- If child develops a rash up to 5 days after challenge, continue to avoid penicillin and refer to Allergist for further evaluation

Penicillin Allergy Delabeling Guideline

Outpatient Clinic Resources for Oral Amoxicillin Challenge

1. Education and resources on oral drug challenge and risks:
 - a. CME Credit for guideline education completion [Children's MN Education Site - CHN Education](#)
 - b. Patient/Family Education - [Penicillin/Amoxicillin Allergy Delabeling](#) handout ([English](#), [Somali](#), [Spanish](#))
 - c. AAAAI Penicillin Allergy Center - <https://education.aaaai.org/penicillin-allergy-center/penicillin>
 - d. JAMA Network- Penicillin Allergy: Evaluation and Testing <https://www.youtube.com/watch?v=peRu21bnNgo>
 - e. Washington State Department of Health, Penicillin Allergy Delabeling - <https://doh.wa.gov/public-health-provider-resources/healthcare-professions-and-facilities/healthcare-associated-infections/antimicrobial-resistance-and-antimicrobial-stewardship/antibiotic-stewardship/penicillin-allergy-delabeling>
 - f. Annals of Allergy, Asthma & Immunology: [Penicillin Delabeling - Ready for pediatric primary care](#)
2. Evaluate Penicillin Allergy Risk - [Penicillin Allergy Questionnaire](#) ([English](#), [Somali](#), [Spanish](#))
 - a. CHN Penicillin Allergy Questionnaire
 - i. No Risk category- Eligible for Penicillin allergy delabeling by history alone
 - ii. Low Risk category- Eligible for Oral Amoxicillin Challenge
 1. Screen for oral challenge exclusion criteria
 - iii. High Risk category- Not-Eligible for Oral Amoxicillin Challenge - refer to Allergist
3. Consent forms for oral challenge - [Consent for Amoxicillin Challenge](#) ([English](#), [Somali](#), [Spanish](#))
4. Oral Challenge Protocol - [Protocol for Oral Amoxicillin Allergy Challenge in Children in Outpatient Setting](#)
5. Office Staffing - Normal staffing ratios are acceptable and 1:1 staffing is not needed (same level of staffing as for routine vaccinations)
6. Allergic Reaction/Anaphylaxis Kit
 - a. Epinephrine
 - i. Auto-injector (e.g. EpiPen) - 0.15mg and 0.3mg
 - ii. Nasal Epinephrine - 1 mg and 2 mg
 - b. Cetirizine (Zyrtec) and/or Diphenhydramine (Benadryl)
 - c. Albuterol MDI and/or nebulized
 - d. Basic clinic CPR training
 - e. Basic clinic life support equipment
 - f. IV equipment - not necessary
7. Amoxicillin available in clinic
 - a. Amoxicillin Powder for reconstitution - [Amoxicillin Oral Challenge Dosing Directions](#)
 - i. Amoxicillin 400mg/5ml - 50 ml bottle
 - ii. Amoxicillin 250mg/5ml - 80 ml bottle
 - iii. Amoxicillin 200mg/5ml - 50 ml bottle
 - b. Capsules/tablets
 - i. Amoxicillin 250mg capsule - bottle of 100
 - ii. Amoxicillin 500mg capsule/tablet - bottle of 100
8. Treatment for Positive Oral Challenge Test Reactions - [Treatment for Positive Oral Challenge Test Reactions](#)



9. Documentation

- a. Visit note documentation in EMR – [Clinic Visit Note Amoxicillin Challenge](#)
- b. Penicillin Allergy Documentation - delabel or keep penicillin allergy based on challenge result, document oral amoxicillin challenge date and results in notes for the appropriate type of reaction
 - i. Clarify Type of Drug Reaction
 1. Drug Allergy
 2. Drug Adverse Reaction
 3. No Drug Related Reaction
 - ii. Locations for Documentation
 1. Patient EMR
 2. Pharmacy
 3. Dentist
 4. School Nurse
 5. Personal Documentation Card and/or Patient Portal Document

10. Insurance Payment for Office Oral Challenge

- a. CPT Codes
 - i. 95076 - *Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); initial 120 minutes*
 1. A minimum of 61 minutes must be spent on the challenge in order to use the 95076 code
 2. 95076 includes the first 2 hours (120 minutes) of the testing which begins when you start discussing the challenge testing at the start of the visit
 3. Because the challenge must be given in “sequential and incremental” doses per the CPT definition, add modifier 52 to code 95076 to indicate only one dose was given
 - a. *Modifier 52 – Reduced Services: Under certain circumstances a service or procedure is partially reduced or eliminated at the discretion of the physician or other qualified health care professional. Under these circumstances the service provided can be identified by its usual procedure number and the addition of modifier 52, signifying that the service is reduced. This provides a means of reporting reduced services without disturbing the identification of the basic service.*
 - ii. 95079 - *each additional 60 minutes of testing (List separately in addition to code for primary procedure)*
 - iii. 99202-99215 - If a patient has a reaction and the oral challenge is discontinued, a problem-oriented evaluation and management code (99202-99215) may be charged in addition to the oral challenge. The same timeframe may not be counted for both the evaluation and management code and the oral challenge.
- b. ICD-10 Codes
 - i. Z88.0 - *Allergy status to penicillin*
 1. Use this code for oral challenges
 - ii. T36.0X5A - *Adverse effect of penicillin, initial encounter*
 1. Use this code as a third listed code if there is a reaction to the penicillin dose given in the oral challenge
 2. Use a second listed code the specific reaction such as L27.0 - *Generalized skin eruption due to drugs and medicaments taken internally*