CLINICAL PATHWAY:
Penicillin Allergy Delabeling

THIS PATHWAY SERVES AS A GUIDE AND DOES NOT REPLACE CLINICAL JUDGMENT.

Inclusion Criteria *(must have all of the following):*

- Patients with history of benign cutaneous reaction without systemic symptoms that started >1 hour after penicillin-based medication or history not consistent with penicillin (PCN) allergy (i.e., family history of penicillin allergy or symptoms such as headache or diarrhea) **and**
- Able to follow up with medical provider or Infectious Diseases (ID) if any reactions occur
- **Note**: patients on room air or with consistently improving low flow oxygen requirement may proceed with pathway if no other exclusion criteria exist

Exclusion Criteria *(any one of the following):*

- Patient in critical or unstable condition
- Patients with current rash, wheezing, increasing oxygen requirement, inability to take oral medications, ongoing emesis
- Currently receiving any steroid >5 days; **or** received daily prednisone ≥2 mg/kg/day (or ≥20 mg/day of prednisone if weight ≥10 kg) or other steroid at equivalent dose for at least 5 days during the past 2 weeks; **or** received pulse dose steroid during the past 2 weeks

- RN or resident will inform primary attending if patient may be eligible
- Attending to verify patient meets inclusion criteria for penicillin allergy delabeling challenge
- Contact on-call ID provider via Voalte if there are questions regarding inclusion/exclusion criteria

History not consistent with allergic reaction (i.e., allergy listed d/t positive FHx of PCN allergy; sxs, such as headache or diarrhea, that are consistent w/known non-allergic adverse effects of antibiotics)

- May be treated with PCN
- Provide family education on allergy vs. adverse antibiotic side effects (provide **Family Handout**)
- Can consider Direct Oral Challenge[2] if preferred by patient/family
- Delabel the patient in Epic

Mild Reaction (i.e., benign cutaneous reaction, such as urticaria > 1 hour after dose)

- Discuss process with patient/caregiver including potential reactions and medications utilized
- Obtain verbal informed consent
- Provide **Family Handout**

Patient/caregiver consent obtained?

NO

- Recommend primary care provider places referral for outpatient allergy (**Appendix A: Allergy Offices for Pediatric Patients**)
- Use alternative antibiotic therapy per standard practice

YES

Severe reaction (i.e., hx of anaphylaxis, angioedema, hypotension) **or** contraindication to drug challenge [1]

- Utilize "Penicillin Allergy Delabeling" order set
- Direct Oral Challenge drug challenge[2]
  - Give **amoxicillin** enterally 45 mg/kg x1 (max 500 mg/dose) regardless of timing of last antibiotic dose
  - If clinically warranted: can use **amoxicillin-clavulanate ES** 45 mg/kg x1 (max 500 mg amoxicillin/dose) instead
  - Monitor for 1 hour post-administration
- Nursing:
  - At 15 minutes and 1-hour post-administration: assess for symptoms such as rash, angioedema, wheezing, and any patient/caregiver concerns. If any reaction, contact provider to evaluate patient and obtain complete set of vitals.
  - Notify provider immediately if any reaction occurs

[2]**Direct Oral Challenge**:

- Does not have to be timed in relation to patient's current antibiotic regimen
- Does not have to wait until discharge and can be done sooner if patient meets criteria (e.g., taking enteral meds, no wheeze)

Reaction to drug challenge?

YES

Immediate (IgE-mediated) reaction

Occurs within 1 hour and can present as urticaria, angioedema, exanthem, wheezing, hypoxia, hypotension, anaphylaxis

- Utilize **Anaphylaxis Clinical Pathway**
- If not anaphylaxis, manage symptomatically per provider discretion
- Monitor as per **Anaphylaxis Clinical Pathway** after treatment
- Treat with alternative antibiotic therapy per standard care
- Update allergy section with specific reaction + date

Note: consider consulting Infectious Diseases with non-immediate reactions.

NO

No Reaction within 1 hour post-drug challenge

- If clinical condition requires higher antibiotic dosing than the drug challenge, may complete the remainder of the dose after patient passes the initial challenge above.
- Delabel allergy in Epic by deleting allergy and selecting the reason as "no longer clinically significant". Include in the free text "direct oral challenge tolerated" with the date.
- Document in event note and discharge note that patient was successfully delabeled utilizing ".PenicillinChallenge" SmartPhrase
- Provide appropriate penicillin-based Rx with note to pharmacy that patient tolerated amoxicillin drug challenge

Discharge Instructions

- Provide education on when to suspect a delayed allergic reaction and to call ID at 860-545-9490 or seek medical attention
- Utilize SmartPhrase ".pencillinchallengedc"

[1]**Contraindications to drug challenge**

- Severe cutaneous adverse drug reaction (e.g., SJS/TEN, DRESS, AGEP)
- Febrile neutrophilic dermatosis (Sweet Syndrome)
- Erythema multiforme
- Serum Sickness-like Reaction (SSLR)
- Drug induced autoimmune diseases (e.g., bullous pemphigoid, Pemphigus vulgaris, Linear igA bullous disease, drug induced lupus)
- Other cutaneous drug reactions (e.g., generalized bullous FDE, exfoliative dermatitis)
- Organ specific drug reactions (e.g., cytopenias – anemia, neutropenia, leukopenia, thrombocytopenia; drug induced - liver injury, nephritis, pneumonitis, meningitis, pancreatitis; drug induced vasculitis)
- Leukocytoclastic vasculitis
- Eosinophilic granulomatosis with polyangiitis

References:

- CDC Penicillin Allergy
- Allergy and Clinical Immunology Practice Guideline

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Legal disclaimer:
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