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BETA-LACTAM ALLERGY EVALUATION SERVICE (BLAES)

Beta-Lactam Allergy Evaluation Service provider will complete a screening questionnaire with the patient to determine eligibility for evaluation. Patients may not be a candidate for evaluation for the following reasons:

1. Patients recently on antihistamines. The service may re-evaluate patient after the anti-histamines have been held for a period of time.
2. Patients with active mental status changes or a patient who is unable to communicate clinical symptoms.
3. Patients who are enrolled for hospice care
4. Patients with certain medications such as: those who are actively in respiratory distress, hypotensive (on pressor support and/or systolic blood pressure at 30mm below baseline), or with active urticaria (hives) and/or angioedema (swelling), or other rashes.

Penicillin skin testing, when indicated, will be performed at the bedside by the beta-lactam allergy evaluation service. **The skin testing materials will be delivered to the unit and should be stored in the patient's medication bin and the beta-lactam allergy evaluation service notified of their arrival to the unit (pager 61457).** The details of the penicillin skin test are described in Appendix A.

Full dose drug challenge procedure:

1. This procedure is often performed after a negative penicillin skin test. In low risk individuals as defined by the Beta-Lactam Empiric Therapy Guidance, a full dose drug challenge without prior penicillin skin testing can be performed. The procedure for full dose drug challenge is identical for patients who underwent penicillin skin test and those patients who did not need the skin test. **This challenge does not require 1:1 nursing**.
2. Obtain baseline vital signs (blood pressure, heart rate, respiratory rate, Oxygen saturation).
3. As ordered by the provider, confirm the following medications are available on the unit.:
   a. epinephrine
   b. diphenhydramine (PO & IV)
   c. albuterol
   d. hydrocortisone
   e. glucagon (if patient is on a beta-blocker)
4. Peripheral or central IV access must be available during the drug challenge in the event parenteral medication is necessary
5. One dose of the drug will be ordered by beta lactam allergy evaluation service provider. This can be either orally or by IV depending on the medication
6. Bedside RN will be administering medication as directed by order.
7. Vital signs (specifically heart rate, blood pressure, O2 sat, respiratory rate) at 15 minute intervals over 60 minutes should be performed by bedside RN.
8. If any of the following signs and symptoms are noted during the 60-minute dose challenge, contact the primary team and the Beta-Lactam Allergy Evaluation Service first contact and initiate anaphylaxis/hypersensitivity treatment per the orders provided. **The Beta-Lactam Allergy Evaluation provider/NP can be reached at 734-803-1040 or pgge 61457.**
   a. Hives or rash
   b. Swelling of the throat triggering shortness of breath or difficulty breathing
   c. coughing, wheezing, shortness of breath
   d. Sudden drop in the oxygen saturation below 90% with coinciding shortness of breath or difficulty breathing
   e. abdominal pain with or without vomiting
   f. Hypotension – less than 80 mm Hg systolic or symptomatic change from baseline
   g. Loss of consciousness.
9. If no symptoms develop after the one-hour observation period, the Beta-Lactam Allergy Evaluation Service provider will update the medication allergy section with the results, complete documentation of the evaluation in MiChart, and notify the primary team of the outcome.
10. If symptoms develop and the patient requires treatment, the beta-lactam allergy service will update the details of the patient's beta-lactam allergy label, including the date of the BLAES evaluation. Primary team will be notified of the result.

10/90 Dose Drug Challenge Procedure:

10/90 dose drug challenge may be recommended by BLAES in certain circumstances. These are typically done with IV medications, but sometimes used with PO medications. BLAES will place orders in collaboration with the primary team. However, the primary team holds responsibility for the patient during the challenge. A 1:1 nurse is required for the duration of the challenge.

1. A provider **must be available in house or available by phone or page. In the intensive care units, the provider must be present on the unit. The provider should be available** from the time the first dose is administered until 1 hour following the second dose. Once the challenge has started, please make sure that the responsible Provider is aware.
2. **1:1 nursing is required.**
3. Vital signs including RR, BP, HR and pulse ox should be monitored and documented every 15 minutes from the start of the drug infusion or drug ingestion (if PO) until 1 hour after the last dose is completed.
4. An anaphylaxis treatment kit containing epinephrine and diphenhydramine must be at the bedside during the challenge procedure. For a patient who is on Beta Blocker, Glucagon must also be at the bedside.
    a. During treatment for anaphylaxis always give Epi first, but if ineffective and the patient is on a beta blocker, 1 to 2 mg of IV glucagon should be given over 5 minutes followed by 0.3-0.9 mg/hr IV.
5. Oxygen and suction setup must be at the bedside.
6. The patient is initially administered 10% of the dose (i.e., nafcillin 100 mg).
7. If no clinical symptoms develop, the patient will be administered the remaining 90% of the target dose (i.e., nafcillin 900 mg) followed by an additional 60-minute observation period after dose completion. Vital signs will be monitored every 15 minutes for this period as well.
8. **If the patient has a reaction during challenge, please document the time the reaction occurred in relation to the last dose of medication given, as well as any objective physical findings or change in vital signs.**
    a. For warm sensations or rash, stop the challenge, notify the physician responsible for the patient and administer diphenhydramine PO as ordered and contact BLAES (pager # 61457)
    b. For respiratory distress, generalized hives, hypotension, or other life-threatening reactions, stop the challenge, call the provider responsible for the patient STAT and administer epinephrine IM as ordered and diphenhydramine IV. The provider must then contact BLAES (pager # 61457) for further instructions.
    c. The Rapid Response Team should be notified if the patient does not respond to initial treatment with epinephrine. (See Appendix B – Michigan Medicine Anaphylaxis Protocol)

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Appendix A – Penicillin Skin Testing Procedure

The penicillin skin testing order set will be placed by the Beta-Lactam Allergy Evaluation Service provider. **The unit will receive the skin testing material from B2 pharmacy.** Penicillin G, Pre-Pen, Saline, and Histamine control will be preloaded into syringes at the appropriate concentration:

1. Negative Control: Sodium chloride solution without preservative
2. Penicillin G 10,000 units/mL (a minor determinant)
3. Pre PEN (benzylpenicilloyl polylysine) full strength (major determinant)
4. Positive Control: Histamine base 1 mg/mL (histamine phosphate 0.275 mg/mL).

The patient's identity will be verified by the provider using the patient's full name and date of birth. The provider will answer any questions from the patient, but a written consent is not necessary.
If the patient has agreed and does not have any additional questions, the provider will proceed with **skin prick test** as described below:

1. Visualize the volar aspect of the forearm and upper arm for any findings that may interfere with skin testing such as bruising, rashes, or tattoos. Create a clearly visible border around these findings with a marker.
2. Clean the volar aspect of one forearm with an alcohol swab.
3. Using the marker provided, label the forearm as follows:
    a. PRP, PG, - , and + (PRP refer to PrePen, PG refers to Penicillin G, + refers to positive control and – refers to negative control).
4. Drop test material on the volar aspect of the forearm, matching the labeled syringe to the corresponding test.
5. Press down and twist through each drop using a different dermapik to the patient's forearm at the placed drops for each of the four testing reagents.
6. After 15 minutes, measure the widest diameter of the bump (wheal) and the redness (flare) in millimeters using the ruler in the box and record in the penicillin allergy skin prick testing template in MiChart.
    a. If the positive control wheal size measures at least 3 mm greater than the saline control, then the test can be interpreted.
    b. If the positive control wheal is less than 3 mm greater than the saline control, then the skin test cannot be interpreted, and the no further evaluation can be made at this time. The penicillin allergy evaluation must be stopped at this time. Review any potential medications that could be blocking the test. If there are medications blocking the skin test that can be withheld, re-evaluate the patient after those medications have been withheld for three days.
    c. If the skin test has a positive control at least 3 mm greater than the saline control AND the skin test result to either PrePen or Penicillin G or both is positive (defined as 3mm greater than the negative control), then the patient has a positive test. The date and result of the Penicillin skin test must be noted in the patient medication allergy section in MiChart.
    d. If the skin test has a positive control at least 3mm greater than the saline control AND the skin test to both the PrePen and Penicillin G is non-reactive, then proceed with the intradermal test.
7. The **Intradermal test** is applied to the outer aspect of the upper arm. Check the skin on both upper arms and mark any rashes, bruising, or tattoos.
8. Clean the designated testing area with an alcohol swab.
9. Using the marker provided, label the outer aspect of the upper arm with five test sites:
    a. PRP, PRP, PG, PG, and - (PRP refer to PrePen, PG refers to Penicillin G, and - refers to saline control)
10. Apply each of the five testing agents intradermally, making a 2-3 mm bleb at each test site, matching the labeled syringe to the labeled skin testing site. Draw a circle around each of the bleb to mark the boundary.
11. After 15 minutes, measure the widest diameter for the bump (wheal) and the redness (flare) in millimeters using the skin testing ruler in the box and record in the penicillin allergy intradermal testing template in MiChart.
    a. If the reading of any of skin tests at 15 minutes reveals an increase in the size of the wheal (bump) by 3 mm greater than the diameter when the test was first placed, then the test is considered positive.
    b. **Matching positive results**: If both PRP skin tests and/or both PG skin test meet criteria for a positive result, then the patient has a positive test and must continue to avoid penicillin products.

c. **Mismatching results**: If only one out of the two PRP or only one out of the two PG skin tests meet criteria for a positive result, then it is advisable to repeat the intradermal test on the other arm to the test that is mismatching. Wait another 15 minutes and measure the diameter as before. Use the result found in 3 out of 4 of the results.

   e.g., PRP has one positive and one negative and PG has two negatives on the first intradermal test. Apply two more PRP intradermal test on the opposite arm. If the second PRP intradermal test reveals two negative results, then 3 out 4 tests are negative and the PRP is labeled negative. If the second PRP intradermal test reveals two positive results, then 3 out of 4 tests are positive and the PRP is labeled positive. If there is still a mismatched result on the 2nd PRP intradermal test, then is it considered an indeterminant result. Clinical correlation is recommended to determine if drug challenge can be performed.

d. **Matching negative results**: If the skin test to all four skin tests are negative then proceed with the full dose challenge.

Appendix B ANAPHYLAXIS PROTOCOL

Reference the ADULT University of Michigan Health System Viewing UMH Emergency Management of Infusion Related or Hypersensitivity Reactions Policy, 07-01-014 Exhibit A ADULT (policystat.com)

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