ACUTE GROUP A STREPTOCOCCAL (GAS) PHARYNGITIS INFECTION STATEWIDE PROTOCOL

Iowa Board of Pharmacy

I. Purpose

This statewide protocol specifies the criteria and procedures for a pharmacist to initiate CLIA-waived point-of-care testing and, when indicated, the dispensing of antibiotic therapies to treat acute Group A streptococcal (GAS) pharyngitis infection. The purpose of this protocol is to ensure appropriate and timely antibiotic therapy for individuals with GAS pharyngitis following diagnostic confirmation via a CLIA-waived point-of-care test.

II. Authority

Pursuant to Iowa Code section 155A.46, a pharmacist may order and administer point-of-care testing and treatment pursuant to a protocol developed by the Iowa Board of Pharmacy ("board") in consultation with the Department of Public Health to individuals aged six (6) years and older, only in accordance with this protocol. For the purpose of this protocol, the pharmacist's order shall constitute a prescription. For the purpose of this protocol, "pharmacist" shall include a licensed pharmacist or registered pharmacist-intern who has completed the training requirements identified in Section III (Qualification). Pursuant to rule 657—3.21(155A), non-clinical, technical functions may be delegated to a pharmacy technician who has documented training in the function being delegated and who is under the supervision of a pharmacist.

III. Qualification

Prior to initiating GAS pharyngitis testing and dispensing of antibiotic therapy under this protocol, ~~a pharmacist~~ all individuals who will be involved in testing shall document successful completion of education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the ~~pharmacist~~pharmacy.

Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures. Required training shall be successfully completed via a program accredited by the Accreditation Council for Pharmacy Education (ACPE) or pre-approved by the Board. A registered nurse who is licensed pursuant to Iowa Code 152 or 152E is deemed to have met the training requirement for patient specimen collection.

Additionally, a pharmacist shall document successful completion of at least one (1) hour of ACPE-approved continuing education related to streptococcal infection during the

pharmacist's license renewal period during which the pharmacist is engaged in point-of-care testing and treatment for GAS pharyngitis.

The pharmacist shall be familiar with the current Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis by the Infectious Disease Society of America (IDSA).

IV. Criteria to initiate CLIA-waived diagnostic test

Any individual who meets ALL of the following criteria is eligible for CLIA-waived diagnostic testing:

1. Age six (6) years or older (with consent of parent/guardian if < 18 years old), and
2. Complaint of ANY sign or symptom consistent with GAS pharyngitis (sore throat, pain on swallowing, fever, headache, swollen or tender cervical lymph nodes, inflamed or swollen tonsils or uvula).

If an individual does not qualify for testing under this protocol, the pharmacist shall refer the individual to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

V. Patient evaluation

A. *Medical and social history*. The pharmacist shall collect and evaluate the following medical and social history:
   a. Past medical history,
   b. Current clinical comorbidities or disease states, including current mental status,
   c. Current blood pressure, pulse, respiratory rate, temperature, and weight
   d. Relevant social history,
   e. For females of child-bearing potential, pregnancy or breastfeeding status
   f. Current medication use, and
   g. Allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction).

B. *Exclusion criteria*. Upon evaluation of the medical and social history in paragraph A, the pharmacist shall not dispense antibiotic therapy to a patient who meets ANY of the criteria listed herein and shall refer the patient to their primary care provider or other urgent/emergency treatment facility as clinically appropriate:
   a. Pregnant or breastfeeding,

b. Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS),
c. History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS-induced glomerulonephritis,
d. Antibiotic therapy prescribed for sore throat or upper respiratory infection within the previous 30 days,
e. Clinical instability based on the pharmacist's clinical judgment or any of the following conditions:
    i. Acute altered mental status,
    ii. Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg,
    iii. Pulse > 125 beats/minute,
    iv. Respiratory rate > 30 breaths/minute, or
    v. Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit, or
f. Presenting with overt viral features (rhinorrhea, cough, oral ulcers, and/or hoarseness).

Patients who do not qualify for antibiotic therapy in response to testing under this protocol shall be referred to a primary care or urgent/emergency treatment facility as clinically appropriate for additional evaluation when the pharmacist has a high suspicion of a false-negative result, determines that the patient is at high risk for complications, or otherwise considers additional care to be in the best interest of the patient.

VI. Evaluation of CLIA-waived ~~diagnostic test~~ Rapid Antigen Detection Test (RADT) result

The pharmacist shall evaluate the result of the test and provide the result to the patient or caregiver.

A. *Negative test result*.
    a. For patients aged 18 years and older, no back-up throat culture is needed. ~~In the event that a patient's test produces a negative result for GAS pharyngitis, the~~ The pharmacist shall counsel the patient or caregiver on the risk of a false-negative test result and on appropriate self-care (get plenty of rest, drink plenty of fluids, treat symptoms as needed, etc.) or shall refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate. Such referral shall be made when the pharmacist has a high suspicion of a false-negative result,

determines that the patient is at high risk for complications, or otherwise considers additional care to be in the best interest of the patient.

b. For patients aged six (6) to <18 years, back-up throat culture is required and the patient shall be referred to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

B. *Positive test result*. ~~In the event that a patient's test produces a positive result for GAS pharyngitis, the pharmacist shall perform a differential Rapid Antigen Detection Test (RADT) to identify acute GAS or viral pharyngitis.~~

a. ~~If RADT is positive, the~~ The pharmacist may proceed to consideration for antibiotic therapy treatment.

~~*b.* If RADT is negative,~~

~~i. For patients aged 18 and older, no back-up throat culture is needed and the pharmacist shall follow the parameters of paragraph A.~~

~~ii. For patients aged six (6) to <18, back-up throat culture is required and the patient shall be referred to a primary care provider or urgent/emergency treatment facility as clinically appropriate.~~

VII. Medications authorized

The pharmacist is authorized to order and dispense the following antibiotic agents, unless an identified contraindication applies for the patient, including selection of the product and dosage form deemed appropriate and in the best interest of the patient. If the pharmacist has a recent patient creatinine level and current weight, the pharmacist may adjust the medication dose per the manufacturer package insert for patients with CrCl < 30.

A. First-line treatment
   a. Amoxicillin
      i. Contraindication
         1. Penicillin allergy
      ii. Dosing
         1. 25 mg/kg (max 500 mg) PO twice daily x 10 days, or
         2. 50 mg/kg (max 1,000 mg) PO once daily x 10 days

B. Second-line treatment (for patients with mild allergic reactions, e.g. rash, to penicillin)
   a. Cephalexin
      i. Contraindications
         1. Cephalosporin allergy
         2. Severe penicillin allergy
      ii. Dosing
         1. 20 mg/kg/dose (max 500 mg/dose) PO twice daily x 10 days

C. Third-line treatment (for patients with mild allergic reactions, e.g. rash, to penicillin or cephalosporins or severe reactions, e.g. anaphylaxis, to penicillin)
    a. Azithromycin
        i. Contraindication
            1. Macrolide allergy
        ii. Dosing
            1. 12 mg/kg (max 500 mg) PO once daily x 5 days
    b. Clindamycin
        i. Contraindication
            1. Clindamycin allergy
        ii. Dosing
            1. 7 mg/kg/dose (max 300 mg/dose) PO three times daily x 10 days
    c. Clarithromycin
        i. Contraindication
            1. Macrolide allergy
        ii. Dosing
            1. 7.5 mg/kg/dose (max 250 mg/dose) PO twice daily x 10 days
D. The pharmacist may recommend the following adjunctive therapy for treatment of moderate to severe symptoms or control of high fever associated with acute GAS pharyngitis, unless contraindicated:
    a. Acetaminophen PO according to OTC dosing recommendations, and
    b. Ibuprofen PO according to OTC dosing recommendations.

VIII. Labeling

A prescription label shall be affixed to the antibiotic product as required in rule 657—6.10(155A).

IX. Patient education required

The pharmacist shall counsel and educate the patient on appropriate self-care, including symptom control, hygiene, and infection control measures, and IDSA guidelines which recommend the patient stay home from work, school, or daycare until they are afebrile and until 24 hours after initiation of appropriate antibiotic therapy. A pharmacist ordering and dispensing antibiotic therapy under this protocol shall provide the following:

1. Medication counseling consistent with state and federal requirements for prescription drug products, and
2. Instructions on signs and symptoms that warrant emergency medical care.

X. Monitoring and follow-up

No additional follow-up laboratory test(s) shall be required. A pharmacist shall follow up with the patient or caregiver within 24 to 48 hours of dispensing for evaluation of therapy, the need for additional medical intervention, clinical stability, symptom burden, and medication adverse effects. The pharmacist shall refer the patient to a primary care provider or urgent/emergency treatment facility if any of the following are reported:

a. Significant deterioration in condition or new evidence of clinical instability,
b. Lack of improvement in symptoms or onset of symptoms indicative of serious complications, or
c. Medication adverse effects severe enough to warrant discontinuation of therapy.

XI. Protocol, facility and equipment

A pharmacist who orders and administers GAS pharyngitis CLIA-waived diagnostic testing and dispenses antibiotic therapies pursuant to this protocol shall maintain a current copy of this protocol and an appropriately private area for patient testing and counseling at each location at which the pharmacist engages in the protocol activities. A pharmacist shall ensure that the following supplies are readily available when engaged in the activities identified in this protocol:

1. Testing equipment and associated supplies
2. Scale
3. Blood pressure cuff (appropriately sized for the patients treated)
4. Thermometer (oral, tympanic, or temporal)

XII. Documentation

The pharmacist shall maintain via patient record or electronic health record the following documentation for each patient who is tested for GAS pharyngitis under this protocol:

1. The presenting signs and symptoms that warranted GAS pharyngitis testing,
2. The parental/guardian consent for patients under the age of 18 years,
3. The patient's medical and social history collected by the pharmacist,
4. The manufacturer, lot, expiration date, and result of the test used to determine GAS pharyngitis status,
5. Required elements for the dispensing of prescription medication, if dispensed, pursuant to board rule 657—6.8(155A),

6. The patient's attestation that they received and expressed understanding of the required counseling and education, and
7. The rationale for the antibiotic selected.

XIII. Notification

A. *Medication dispensed*. For patients who were dispensed antibiotic therapy in response to a positive test result, the pharmacist shall provide the patient's primary care provider with a summary of the encounter within two (2) business days to include, at a minimum, the following:
    1. The patient's name and date of birth,
    2. GAS pharyngitis test result,
    3. Medication dispensed, and
    4. Follow-up plan.

B. *Positive test result with no medication dispensed*. For patient who received a positive test result, but who were ineligible for or declined antibiotic therapy, the pharmacist shall provide the patient's primary care provider with a summary of the encounter within two (2) business days to include, at a minimum, the following:
    1. The patient's name and date of birth,
    2. GAS pharyngitis test result, and
    3. Contraindication or reason that antibiotic therapy was not dispensed.

C. *Negative test result*. For patients who received a negative test result, the pharmacist may, but is not required to, provide the patient's primary care provider with a summary of the encounter with information as determined by the pharmacist's clinical judgment.

D. *No primary care provider*. In any of the situations in paragraphs A through C, if the patient or caregiver does not identify a primary care provider, the pharmacist shall provide the patient with a written record of the encounter and advise the patient to consult with an appropriate health care professional of the patient's choice.

XIV. Effective date

This protocol is effective September 1, 2021 and shall be in effect for a period of one year and shall automatically renew for subsequent one year periods unless otherwise amended or terminated by the board.