

ACUTE GROUP A STREPTOCOCCAL (GAS) PHARYNGITIS INFECTION PROTOCOL

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of antibiotics 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 streptococcal pharyngitis following diagnostic confirmation via CLIA-waived point-of-care Rapid Antigen Detection Test (RADT) or CLIA-waived real-time Polymerase Chain Reaction (PCR) test.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing antibiotics under this protocol, pharmacist(s) must have received education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy (RADT and/or PCR) from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Iowa Board of Pharmacy.

CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antibiotics to treat acute GAS infection will treat individuals according to current IDSA guidelines.¹

Inclusion criteria:

Any individual who presents to the pharmacist and meets **ALL** of the following inclusion criteria:

- Age 6 years or older (with consent of a parent/guardian if < 18 years old)
- 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)
- Positive GAS result via CLIA-waived point-of-care RADT or PCR

Exclusion criteria:

Any individual who meets **ANY** of the following criteria:

- Age < 5 years old
- Pregnant or breastfeeding
- Renal dysfunction (based on individual's report or pharmacy records)
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 continuous weeks, HIV/AIDS)
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS induced glomerulonephritis

¹ 1 Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis: 2012 Update by the Infectious Diseases Society of America. Available online at: http://www.idsociety.org/Guidelines/Patient_Care/IDSA_Practice_Guidelines/Infections_By_Organ_System-81567/Lower/Upper_Respiratory/Streptococcal_Pharyngitis/

- Other antibiotic therapy prescribed for sore throat or upper respiratory infection within the previous 30 days
- Clinically unstable based on the clinical judgment of the pharmacist or any of the following criteria:
 - Acute altered mental status
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
 - Pulse >125 beats/min
 - Respiratory rate >30 breaths/min
 - Temperature >103 °F (taken orally)
- Presenting with overt viral features, such as: rhinorrhea, cough, oral ulcers, and/or hoarseness

Commented [CF1]: Feedback received that these parameters may be normal for some; may have to be adjusted

Individuals who do not qualify for RADT or PCR under this protocol will be referred to a primary care provider or urgent/emergent treatment facility as clinically appropriate. Individuals who do not qualify for antibiotic dispensing following RADT or PCR will be referred for additional evaluation when the pharmacist has high suspicion of a false negative result, determines that the individual is at high risk for complications, or otherwise considers additional care to be in the best interest of the individual.

MEDICATIONS

This protocol authorizes pharmacist(s) to initiate the dispensing of one of the following medication regimens to an individual meeting criteria:

First-line Treatment (unless contraindicated due to history of penicillin allergy)

1. Amoxicillin PO 25mg/kg (max = 500 mg) twice daily for 10 days or 50 mg/kg (max 1000 mg) once daily for 10 days

Second-line Treatment (for those with mild allergic reactions e.g. rash to penicillin)

2. Cephalexin PO 20 mg/kg/dose (max 500 mg/dose) twice daily for 10 days

Third-line Treatments (for those with mild allergies to penicillin and cephalosporins or severe reactions e.g. anaphylaxis to penicillin)

3a. Azithromycin PO 12 mg/kg (max 500 mg) once daily for 5 days

3b. Clindamycin PO 7 mg/kg/dose (max 300 mg/dose) three times daily for 10 days

3c. Clarithromycin PO 7.5 mg/kg/dose (max 250 mg/dose) twice daily for 10 days

Adjunctive therapy may be useful for treatment of moderate to severe symptoms or control of high fever associated with acute GAS pharyngitis and should be considered as an adjunct to an appropriate antibiotics.

Acetaminophen PO; follow OTC dosing recommendations

Ibuprofen PO; follow OTC dosing recommendations

PROCEDURES FOR INITIATION OF THERAPY

Perform RADT to determine between acute GAS and viral pharyngitis

- If positive, continue to evaluate with protocol

- If negative,
 - Adult: no back up throat culture needed for adults
 - Children and adolescents (<18 y/o): back up throat culture must be done, thus referral to primary care provider or urgent treatment center is required

Antibiotic therapy will be initiated only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Assess for Relevant Medical and Social History

- Patient demographics and weight if <18 y/o using scale in pharmacy
- Medical history
- Relevant social history
- Current Medications
- Medication allergies and hypersensitivities

Evaluate for Contraindications and Precautions

- Mild allergic reactions to penicillin (amoxicillin)
- Mild allergic reactions to cephalosporins (cephalexin)
- Severe allergic reactions to penicillin (amoxicillin and cephalexin)
- Allergic reactions to macrolides (azithromycin and clarithromycin)
- Allergic reactions to clindamycin

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Selection of antibiotic regimen will follow the ordered preference listed above. A lower ranked regimen will only be prescribed if the individual or pharmacy record indicates a drug allergy or other contraindication to a higher-ranked regimen. The pharmacist will assess reported drug allergies for validity by reviewing the individual's pharmacy record and documenting the reported reaction. In any case where amoxicillin is not the selected regimen, the pharmacist will document the clinical reasoning for the selection.

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Telephone follow-up within 24 to 48 hours of dispensing to assess the need for additional medical intervention. Follow-up will assess for clinical stability, symptom burden, and medication adverse effects. Referral to a primary care provider or urgent/emergent treatment facility will occur if any of the following are reported:

- Significant deterioration in condition or new evidence of clinical instability
- Lack of improvement in symptoms or onset of symptoms indicative of serious complications
- Medication adverse effects severe enough to warrant discontinuation

PATIENT EDUCATION REQUIREMENTS

All individuals tested under this protocol will receive counseling on:

- Appropriate self-care, including symptom control, hygiene, and infection control measures.
- Per IDSA guidelines people with acute GAS pharyngitis should stay home from

work, school, or daycare until they are afebrile and until 24 hours after starting appropriate antibiotic therapy

Individuals receiving antibiotics under this protocol will also receive the following:

- Medication counseling consistent with state and federal requirements for prescription drug products
- Instructions on signs or symptoms that warrant emergent medical care
- Follow-up details

DOCUMENTATION

Pharmacist(s) will document via patient record or electronic health record each person who is tested for GAS under this protocol, including:

- Documentation as required for the dispensing of prescription medication
- Documentation of the presenting signs and symptoms that warranted testing
- Documentation of the manufacturer, lot, expiration date, and result of the point-of-care RADT or PCR used to determine GAS status
- Documentation that the individual (or caregiver) received the education required by this protocol
- Documentation of clinical follow up as appropriate
- Documentation of choice of antibiotic and rationale for this particular choice

NOTIFICATION

Pharmacist(s) shall ask all persons tested under this protocol for the name and contact information of a primary care provider. If an individual (or caregiver) identifies a primary care provider, the pharmacist will provide that provider with a summary of the encounter, including at least the individual's name, date of birth, GAS test results, medication dispensed, and follow-up plan, within 2 business days. If the person tested does not have a primary care provider, the pharmacist shall recommend visiting a primary care provider.