Azithromycin Quantity Limit

| Override(s) | Approval Duration |
|----------------|--|
| Quantity Limit | Cystic Fibrosis, Mycobacterium Avium Complex – 1 year |
| | HIV AND Bartonella – 3 months |
| | All other diagnosis – per fill |

| Medications | Quantity Limit |
|---|--|
| azithromycin 250mg | 6 Tablets per fill; 1 fill per 30 days |
| azithromycin 500mg | 3 Tablets per fill; 1 fill per 30 days |
| azithromycin 600mg | 8 Tablets per fill; 1 fill per 28 days |
| azithromycin 1gm powder packets | 2 packets per fill; 1 fill per 30 days |
| azithromycin 100mg/5mL Suspension (15 mL bottle) | 15 mL per fill; 1 fill per 30 days |
| azithromycin 200mg/5mL Suspension (15 mL bottle) | 15 mL per fill; 1 fill per 30 days |
| azithromycin 200mg/5mL Suspension (22.5 mL bottle) | 67.5 mL per fill; 1 fill per 30 days |
| azithromycin 200mg/5mL Suspension (30 mL bottle) | 60 mL per fill; 1 fill per 30 days |

APPROVAL CRITERIA

- I. For individuals diagnosed with chronic sinusitis, approve the following:
 - A. Up to 12 tablets of azithromycin 250 mg (2 Z-Paks); OR
 - B. Up to 6 tablets of azithromycin 500 mg/fill; OR
 - C. Up to 75 mL azithromycin 100 mg/5 mL; OR
 - D. Up to 75 mL of azithromycin 200 mg/5 mL; OR
 - E. Up to 3 azithromycin 1 gram packets;

OR

- II. For individuals diagnosed with Babesiosis by one of the following (IDSA, 2018):
 - A. Positive blood smear for Babesia; OR
 - B. Positive polymerase chain reaction (PCR) for *Babesia*, approve the following quantity (AFHS):
 - 1. Up to 11 tablets of azithromycin 250 mg; **OR**
 - 2. Up to 10 tablets of azithromycin 500 mg; **OR**
 - 3. Up to 10 tablets of azithromycin 600 mg; **OR**
 - 4. Up to 150 mL azithromycin 100 mg/5 mL; OR
 - 5. Up to 150 mL azithromycin 200 mg/5 mL;

- III. For individuals diagnosed with Lyme disease (*Borrelia burgdorferi* infections), approve the following (AHFS):
 - A. Up to 20 azithromycin 250 mg tablets per 30 days; OR
 - B. Up to 10 azithromycin 500 mg tablets per 30 days; OR
 - C. Up to 135 mL azithromycin 100 mg/5 mL per 30 days; OR
 - D. Up to 135 mL azithromycin 200 mg/5 mL per 30 days;

OR

- IV. For individuals diagnosed with pelvic inflammatory disease, approve the following (AHFS):
 - A. Up to 9 azithromycin 250mg tablets per fill; OR
 - B. Up to 5 azithromycin 500mg tablets per fill; OR
 - C. Up to 60 mL azithromycin 100 mg/5 mL per fill; OR
 - D. Up to 60 mL azithromycin 200 mg/5 mL per fill; OR
 - E. Up to 3 azithromycin 1 gram packets per fill;

OR

V. For individuals diagnosed with mycobacterium avium complex (MAC) A. Approve the amount requested:

OR

VI. For individuals diagnosed with cystic fibrosis (CF): A. Approve amount requested;

OR

VII. For individuals diagnosed with toxoplasmosis caused by *Toxoplasma gondii* (AHFS):
A. Approve the amount requested;

OR

- VIII. For individuals diagnosed with pneumonia requiring initial IV therapy, approve the following (AHFS):
 - A. Up to 16 azithromycin 250 mg tablets per fill; OR
 - B. Up to 8 azithromycin 500 mg tablets per fill; **OR**
 - C. Up to 105 mL azithromycin 100 mg/5 mL per fill; OR
 - D. Up to 105 mL azithromycin 200 mg/5 mL per fill;

OR

- IX. For individuals diagnosed with gonorrhea, approve the following:
 - A. Up to 8 azithromycin 250 mg tablets per fill; **OR**
 - B. Up to 4 azithromycin 500 mg tablets per fill; OR
 - C. Up to 60 mL of azithromycin 100 mg/5 mL per fill;

OR

- X. For pediatric individuals diagnosed with pharyngitis or tonsillitis (such as strep throat), may approve the following:
 - A. Up to 5 azithromycin 500 mg tablets; OR
 - B. Up to 75 mL azithromycin 100 mg/5 mL;

XI. For individuals diagnosed with HIV/AIDS AND cryptosporidiosis (*Cryptosporidium parvum*) infection, approve the following (AHFS):
A. Up to 28 azithromycin 600 mg tablets;

OR

- XII. For individuals diagnosed with HIV/AIDS **AND** *Bartonella* infection, approve the following (AHFS):
 - A. Azithromycin 600 mg tablet, one tablet per day for 3 months;

OR

- XIII. For individuals diagnosed with mild to moderate infections caused by *Campylobacter jejuni*, approve the following (AHFS):
 - A. Up to 28 azithromycin 250 mg tablets per fill; OR
 - B. Up to 14 azithromycin 500 mg tablets per fill; OR
 - C. Up to 180 mL azithromycin 200 mg/5 mL;

OR

- XIV. For individuals diagnosed with Legionnaires' disease, approve the following (AHFS):
 - A. Up to 10 azithromycin 250 mg tablets per fill; OR
 - B. Up to 5 azithromycin 500 mg tablets per fill; OR
 - C. Up to 75 mL azithromycin 100 mg/5 mL per fill.

OR

- XV. For individuals using to treat travelers' diarrhea, approve the following (CDC):
 - A. Up to 4 azithromycin 500 mg tablets per fill; OR
 - B. Up to 60 mL azithromycin 100 mg/5 mL per fill.

Key References:

- Centers for Disease Control (CDC). Group A Streptococcal (GAS) Disease. Pharyngitis (Strep Throat). Available at: https://www.cdc.gov/groupastrep/diseases-hcp/strep-throat.html. Last updated: November 1, 2018. Accessed: March 15, 2020.
- Centers for Disease Control (CDC). Travelers' Health-Yellow Book- Chapter 2. The Pre-Travel Consultation Self-Treatable Conditions - Travelers' diarrhea. Available at http://wwwnc.cdc.gov/travel/yellowbook/2018/the-pre-travelconsultation/travelers-diarrhea. Accessed: March 15, 2020.
- 3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: March 15, 2020.
- 4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 5. Lexi-Comp ONLINE[™] with AHFS[™], Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
- Miller JM, Binnicker MJ, Campbell S, et. al. A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2018 Update by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology. Clin Infect Dis. 2018;67(6):e1-e94.

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