

| Market Applicability | | | | | | | |
|----------------------|----|----|----|----|----|----|----|
| Market | DC | GA | KY | MD | NJ | NY | WA |
| Applicable | X | X | X | X | X | X | NA |

Zithromax (azithromycin) Quantity Limit

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

| Medications | Quantity Limit |
|--|--|
| Zithromax (azithromycin) Tablets and Z-Pak 250mg | 6 Tablets per fill; 1 fill per 30 days |
| Zithromax (azithromycin) Tablets and TriPak 500mg | 3 Tablets per fill; 1 fill per 30 days |
| Azithromycin 600mg Tablets | 8 Tablets per fill; 1 fill per 28 days |
| Zithromax (azithromycin) 1gm powder packets | 2 packets per fill; 1 fill per 30 days |
| Zithromax (azithromycin) 100mg/5mL Suspension (15 mL bottle) | 15 mL per fill; 1 fill per 30 days |
| Zithromax (azithromycin) 200mg/5mL Suspension (15 mL bottle) | 15 mL per fill; 1 fill per 30 days |
| Zithromax (azithromycin) 200mg/5mL Suspension (22.5 mL bottle) | 67.5 mL per fill; 1 fill per 30 days |
| Zithromax (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 Zithromax 250 mg (2 Z-Paks); **OR**
 - B. Up to 6 tablets of Zithromax 500 mg/fill; **OR**
 - C. Up to 75 mL Zithromax 100 mg/5 mL; **OR**
 - D. Up to 75 mL of Zithromax 200 mg/5 mL; **OR**
 - E. Up to 3 Zithromax 1 gram packets;

OR

- II. For individuals diagnosed with babesiosis by one of the following (IDSA, 2018):

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- 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 Zithromax 250 mg; **OR**
 - 2. Up to 10 tablets of Zithromax 500 mg; **OR**
 - 3. Up to 10 tablets of Zithromax 600 mg; **OR**
 - 4. Up to 150 mL Zithromax 100 mg/5 mL; **OR**
 - 5. Up to 150 mL Zithromax 200 mg/5 mL;

OR

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

OR

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

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- A. Up to 16 Zithromax 250 mg tablets per fill; **OR**
- B. Up to 8 Zithromax 500 mg tablets per fill; **OR**
- C. Up to 105 mL Zithromax 100 mg/5 mL per fill; **OR**
- D. Up to 105 mL Zithromax 200 mg/5 mL per fill;

OR

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

OR

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

OR

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

OR

- XII. For individuals diagnosed with HIV/AIDS AND *Bartonella* infection, approve the following (AHFS):
 - A. Zithromax 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 Zithromax 250 mg tablets per fill; **OR**
 - B. Up to 14 Zithromax 500 mg tablets per fill; **OR**
 - C. Up to 180 mL Zithromax 200 mg/5 mL;

OR

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

OR

- XV. For individuals using to treat travelers' diarrhea, approve the following (CDC):

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- A. Up to 4 Zithromax 500 mg tablets per fill; **OR**
 B. Up to 60 mL Zithromax 100 mg/5 mL per fill.

Key References:

1. 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.
2. 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-travel-consultation/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.
6. 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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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