QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

ZITHROMAX 250 MG
(azithromycin)

ZITHROMAX Z-PAK 250 MG
(azithromycin)

Status: CVS Caremark Criteria
Type: Quantity Limit; Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS
Zithromax (azithromycin) is a macrolide antibacterial drug indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below. Recommended dosages and durations of therapy in adult and pediatric patient populations vary in these indications.
Adult Patients

- Acute bacterial exacerbations of chronic bronchitis due to *Haemophilus influenzae*, *Moraxella catarrhalis,* or *Streptococcus pneumoniae*.
- Acute bacterial sinusitis due to *Haemophilus influenzae*, *Moraxella catarrhalis.* or *Streptococcus pneumoniae*.
- Sections or subsections omitted from the full prescribing information are not listed.
- Community-acquired pneumonia due to *Chlamydophila pneumoniae*, *Haemophilus influenzae*, *Mycoplasma pneumoniae,* or *Streptococcus pneumoniae* in patients appropriate for oral therapy.
- Pharyngitis/tonsillitis caused by *Streptococcus pyogenes* as an alternative to first-line therapy in individuals who cannot use first-line therapy.
- Uncomplicated skin and skin structure infections due to *Staphylococcus aureus*, *Streptococcus pyogenes*, or *Streptococcus agalactiae*.
- Urethritis and cervicitis due to *Chlamydia trachomatis* or *Neisseria gonorrhoeae*.
- Genital ulcer disease in men due to *Haemophilus ducreyi* (chancroid). Due to the small number of women included in clinical trials, the efficacy of azithromycin in the treatment of chancroid in women has not been established.

Pediatric Patients

- Acute otitis media (>6 months of age) caused by *Haemophilus influenzae*, *Moraxella catarrhalis,* or *Streptococcus pneumoniae.*
- Community-acquired pneumonia (>6 months of age) due to *Chlamydophila pneumoniae*, *Haemophilus influenzae*, *Mycoplasma pneumoniae*, or *Streptococcus pneumoniae* in patients appropriate for oral therapy.
- Pharyngitis/tonsillitis (>2 years of age) caused by *Streptococcus pyogenes* as an alternative to first line therapy in individuals who cannot use first-line therapy.

Limitations of Use
Azithromycin should not be used in patients with pneumonia who are judged to be inappropriate for oral therapy because of moderate to severe illness or risk factors such as any of the following:

- patients with cystic fibrosis,
- patients with nosocomial infections,
- patients with known or suspected bacteremia,
- patients requiring hospitalization, elderly or debilitated patients, or
- patients with significant underlying health problems that may compromise their ability to respond to their illness (including immunodeficiency or functional asplenia)

Off Label Uses
Coronavirus disease 2019 (COVID-19)[2, 3]

INITIAL STEP THERAPY*

**Include Rx (brand and generic) and OTC products unless otherwise stated.*

Initial quantity limits will apply to all claims for azithromycin 250mg tablets or Z-pak (see initial quantity limit chart below).

If the patient has not filled a prescription for the requested medication from the implementation date of this program or within the last 50 days, whichever is first, then the requested drug will be paid under the prescription benefit.

If the patient has filled a prescription for the requested medication from the implementation date of this program or within the last 50 days, whichever is first, then the requested drug will reject for quantity limits exceeded and a prior authorization will be required (see Coverage Criteria section below).

INITIAL QUANTITY LIMIT**

LIMIT CRITERIA

Drug	2 Month Limit*	3 Month Limit*
Zithromax (azithromycin) 250 mg tablets	6 tablets / 50 days	Does Not Apply
Zithromax (azithromycin) Z-pak 250 mg tablets (1 Z-pak contains 6 tablets)	1 Z-pak (6 tablets per Z-pak) / 50 days	Does Not Apply

**The duration of 50 days is used for a 60-day fill period.*

***If the patient is requesting more than the initial quantity limit supply, then the claim will reject with a message indicating that the patient can receive a quantity sufficient to treat COVID-19 and then prior authorization (PA) is required:*

REJECT MESSAGES:

"COVID QL=Six 250 mg tabs or 1 pack per 50 days.

The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is not being prescribed for the treatment of coronavirus disease 2019 (COVID-19) [Note: Initial quantity limits allow for a sufficient quantity of the requested drug to treat coronavirus disease 2019 (COVID-19). A maximum of 6 tablets of Zithromax (azithromycin) 250mg tablets or 1 Z-pak (6 tablets, 250 mg each, per Z-pak) of Zithromax (azithromycin) Z-pak is available without prior authorization.]

REFERENCES

1. Zithromax [package insert]. New York, NY: Pfizer, Inc.; April 2019.
2. Gautret et al. (2020) Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial. International Journal of Antimicrobial Agents – In Press 17 March 2020 – DOI : 10.1016/j.ijantimicag.2020.105949
3. Clinical Pharmacology [database online]. Tampa, FL: Elsevier Inc. Copyright 2020. https://www.clinicalkey.com/pharmacology/. Accessed March 2020.