



➤ HEALTH ALERT: COVID-19 UPDATE

Quantity Limits

Note: Confidio will work in conjunction with the PBMs to monitor the situation and provide updates as we receive them. Confidio previously published a Health Alert outlining emergency protocols for COVID-19 from some PBMs. [The original Health Alert can be accessed here.](#)

(Quantity Limits Health Alert current as of 12:00pm EST, April 1, 2020)

Confidio has begun to see PBMs, and in some cases, state boards of pharmacy, implement the strategy of applying quantity limits for certain drugs currently be used in trials for combating COVID-19. The implementation of these quantity limits is for the purpose of preventing stockpiling. This will assist in not only assuring adequate supplies for COVID-19 clinical trials and investigational use, but to assure adequate and uninterrupted supply for patients who may already be taking these medications for their original FDA-approved indication.

For example, as part of the Confidio Clinical Alert issued 3/17/2020, Confidio identified chloroquine and hydroxychloroquine as part of drug shortage issues within the U.S. due to supply issues related to COVID-19. Nationally, Rheumatologists are trying to reassure patients with lupus or other rheumatic diseases who take these two medications that they will be available and are relatively easy for manufacturers to produce.

The Confidio clinical team has reviewed the PBMs quantity limit implementations and is in favor of establishing and implementing these utilization management limits. A summary of specific PBM steps are as follows:

CVS

Preventing Potential Shortages of Key Drugs:

CVS has introduced a utilization management (UM) product bundle, which will institute quantity limits on medications that potentially treat COVID-19 and are used by members for other conditions.



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Albuterol Meter Dose Inhalers:

- A quantity limit will be added to albuterol inhalers, limiting them to two per 30 days (200 inhalations per device) at retail or six per 90 days at mail.
 - These changes apply only to inhalers and not nebulizer solutions or oral tablets
 - These limits are already commonly used by many CVS clients and are included in some of CVS formulary designs
 - The albuterol limit is not subject to the lookback, so if the member has historically received 3-4 inhalers/mo. and the client implements the QL they will be limited to 2.

Chloroquine, hydroxychloroquine, Kaletra and azithromycin:

A quantity limit will be added to limit the supply dispensed of these drugs:

- Chloroquine, hydroxychloroquine: 10-day supply, limit of one fill per 60 days
- Kaletra: 14-day supply, limit of one fill per 60 days
- Azithromycin 250 mg tablets, limit of 6 tablets or one blister pack of 6 tablets per five days; limit of one fill per 60 days.
- Members are limited to one fill of each product.
- For this sub-category, CVS as a lookback period to identify existing users. Those users will not be impacted.

To minimize disruption for members currently taking these medications, CVS is implementing the following adjudication logic to identify diagnosis and previous utilization to bypass this limit:

1. If a member has filled a 30-day supply within the previous 180 days, the claim will bypass the quantity limit.
2. If the claim comes through with an appropriate non-COVID-19 diagnosis code – including lupus, rheumatoid arthritis (RA) or HIV – the claim will bypass the quantity limit.

If a member does not have: a claim history for these drugs OR a diagnosis code for HIV, lupus or RA, the quantity limit will apply. Prescriptions exceeding the quantity limits or with no diagnosis code will require prior authorization to confirm appropriate use.

Line-of-Business Details:

Employer clients are automatically be opted-in to the quantity limit bundle

- Clients who do not wish to implement these limits must opt-out were required to opt-out by 5 p.m. (CT) on Wednesday, March 25
- Note: The bundle for employer clients is 'all or nothing' – if a client accepts the bundle, they accept all current limits and any changes. Anything else is a custom setup that will require a signed change form from the client and subject to standard implementation timeframes.
- Clients who are unable to meet this deadline will be able to opt-out later. Additional time may be required to implement the opt-out later.

Health plans will need to opt-in to the new UM bundle for commercial, exchange and Medicaid lines of business. Medicare Part D is out of scope currently due to regulatory limitations.



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Express Scripts (ESI)

Clients who are enrolled in the Limited, Advantage, or Advantage Plus AUM Packages or the Limited DQM list will **automatically** receive the following COVID-19 Anti-Stockpiling quantity limits as an auto-update to their current AUM enrollment. **Clients who are not enrolled** in any of these strategies will need to **opt-in** to the COVID-19 Anti-Stockpiling quantity limits.

Generic name	Medication allowed per 365-day period
chloroquine 250 mg tablets	56 tablets
chloroquine 500 mg tablets	28 tablets
Plaquenil (hydroxychloroquine) 200 mg tablets	30 tablets
Kaletra 200 mg/50 mg tablets	56 tablets
Kaletra 100 mg/25 mg tablets	112 tablets
Kaletra 80 mg-20 mg/ml oral solution	160 ml (1 bottle)

Drug	Medication allowed per 90 days
Zithromax (azithromycin) 100 mg/5 ml for oral suspension, 15 ml	13 bottles (195 ml)
Zithromax (azithromycin) 200 mg/5 ml for oral suspension, 15 ml	7 bottles (105 ml)
Zithromax (azithromycin) 200 mg/5 ml for oral suspension, 22.5 ml	5 bottles (112.5 ml)
Zithromax (azithromycin) 200 mg/5 ml for oral suspension, 30 ml	4 bottles (120 ml)
Zithromax (azithromycin) 250 mg tablet	15 tablets
Zithromax (azithromycin) 500 mg tablet	15 tablets
Zithromax (azithromycin) 1 gm single-dose packet	2 packets
Zithromax (azithromycin) 600 mg tablets	24 tablets

MedImpact

On March 26, MedImpact hosted an ad hoc P&T to approve QLs on drugs being used off-label for COVID-19. QL will be added per FDA label maxima, drug detail is provided below. PA was considered but felt it would put an undue burden on populations currently using it for FDA approved indications, such as with hydroxychloroquine being used for patients with lupus or other rheumatic diseases.

Prescriber resources are limited in the current situation and MedImpact chose not to add administrative burden and interrupt appropriate patient therapy. The MedImpact QL being implemented are intended to deter stockpiling. The strategy is across-the-board for standard MedImpact commercial formulary clients. There is no opt-out for standard formularies.

The drugs are:

- Chloroquine phosphate: QL=25 tablets (500 mg) or 50 tablets (250 mg) for 30 days
- Hydroxychloroquine sulfate: QL=90 tablets (200 mg) for 30 days



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- Actemra and Kaletra: Currently awaiting FDA issuance of labeling revision or specific guidance, related to COVID-19
- Remdesivir: IV (pending FDA approval) – QL max 200 mg per fill; Day supply max 100 mg for up to 9 days
- Favipiravir: Pending FDA approval

Optum

Optum is currently working to implement a quantity limit on hydroxychloroquine and chloroquine. OptumRx has existing quantity limits on albuterol inhalers. In order to preserve a continued supply of medication for chronic conditions such as systemic lupus and rheumatoid arthritis while ensuring access to acute use for COVID-19, effective 3/31/2020 OptumRx will be implementing the following quantity limits:

- Hydroxychloroquine will be limited to 30 tablets within a 90-day time period with an automatic bypass (contingent therapy lookback edit) for members who have utilized at least a 60-day supply within the past 120 days.
 - Chloroquine will be limited to 30 tablets (or 40 tablets for 250 mg strength) within a 90-day time period.
- If members require doses of hydroxychloroquine or chloroquine that exceed the quantity limit, their prescribers may complete a prior authorization following Optum's standard process.

WellDyne

As of Monday morning (3/30), WellDyne does not have any additional UM measures in place. Albuterol inhalers are subject to current WellDyne quantity limits.