

Medication Access and Drug Shortage Concerns During the COVID-19 Pandemic: Frequently Asked Questions

American Society of Transplantation Transplant Pharmacy Community of Practice/American College of Clinical Pharmacy Immunology/Transplant Practice and Research Network Medication Access Workgroup

Introduction:

Information regarding COVID-19 is changing rapidly. This document will be updated with the evolving issues related to medication access and drug shortages/supply chain issues within the United States of America during the pandemic.

Medication Access:

1. What should be done to enhance medication home supply?
 - a. During the COVID-19 pandemic, we recommend patients have extra medication on hand as their insurance plan allows. We suggest, on a case-by-case basis, patients contact the dispensing pharmacy or insurance plan and ask about the ability to fill a 90-day supply instead of a 30-day supply. Of note, this may not be possible, depending on the insurance plan, dispensing pharmacy, state law, and specific medications. Also, stability of compounded medications and commercially available liquids (i.e., mycophenolate suspension, valganciclovir suspension, antibiotic suspensions) may be prohibitive. Medicare Part B has historically limited to 30-day medication supplies. There has been some reported success with Medicare Advantage plans and certain Medicaid programs with extended fill supplies. Some insurance plans require use of specific mail order pharmacies to obtain 90-day supplies and some medications have quantity limits. If patients are eligible for 90-day supply of medications, they should be advised to contact their prescribing provider for a 90-day supply prescription, if not already available. If patients are unable to get 90-day supply of medication, they may still be eligible for early medication refills of the 30-day supply since many insurance plans have waived or relaxed their refill policies. Patients should also be advised to contact the transplant clinic as soon as possible if they are having difficulty obtaining medications, or if they have questions/concerns regarding their prescriptions after calling the pharmacy and/or insurance plan. Lastly, requests for extended supplies of medications should be limited to patients on stable or established doses and must be balanced with risk of creating potential drug shortages.
2. Have any of the state Medicaid programs made adjustments because of COVID-19?
 - a. Yes, use this link to check what your state has done. Note that this link may not work on some devices or browsers.
<https://docs.google.com/spreadsheets/d/1ux6a2ZK2eNHvbvsPdIphBT5lgJlx4a1hnMIB3p2XAfk/edit?usp=sharing>
3. Have there been issues with early refill requests?
 - a. Payers may or may not allow members to obtain early refills due to COVID-19. For retail pharmacists: if a patient requests an early refill due to this reason, and if in your professional judgment filling the prescription(s) early is in the best interest of the patient, and if claim is rejected, attempt to submit a Submission of Clarification Code of 13.

Follow the specific payer override processes listed as follows or refer the member to call their plan for further assistance. If the override is approved and the patient uses a copay card, most companies are allowing the early refill on the copay card (see information below regarding use of copay cards to assist with patient out of pocket costs). Also, consider emergency refill requests and quantity limit exception requests.

4. From a pharmacy perspective, which strategies can be utilized to enhance social distancing?
 - a. Telehealth
 - b. Mail order pharmacy
 - c. Medication home delivery through outpatient pharmacy
 - d. Drive through/curbside pick up
 - e. Use of a support person for pick-up
5. What strategies can be used to expedite medication access when faced with insurance mandates, including prior authorizations, step therapy requirements, and specialty mail-order pharmacy mandates?
 - a. Overrides often available for specialty medications to be filled at local retail pharmacies if urgently needed
6. How should we handle loss of employment?
 - a. Involve social work to navigate government assistance/insurance
 - b. Be aware of emergency enrollment periods for state health exchanges
 - c. See below for patient assistance programs to assist with emergency supplies between coverage gaps
 - d. Utilize *PhPRMA's* Medicine Assistance Tool (MAT) (<https://mat.org/>), a search engine designed to help patients, caregivers and health care providers learn more about the resources available through the various biopharmaceutical industry programs. MAT is not its own patient assistance program, but rather a search engine for many of the patient assistance resources that the biopharmaceutical industry offers.
7. What are the available resources for patient assistance programs and copay cards?
 - a. Many resources are available for brand name products through the pharmaceutical manufacturers
 - i. Copay Cards: Help cover a portion of patient out of pocket expenses up to a certain amount annually. These can only be used with commercial insurance if the prescription costs are partially covered by the insurance plan (e.g. - patient's with Medicare or no insurance are not eligible to use copay cards).
 - ii. Patient Assistance Programs: Provide medications at no cost, typically through a mail order pharmacy designated by the manufacturer for patients meeting certain criteria, which may include, but not limited to:
 1. Annual household income
 2. Percent of out of pocket medication expense in relation to annual household income
 3. If applicable, insurance denials, including unsuccessful appeals
 - b. Patients may require new prescriptions for many patient assistance programs and copay card programs with DAW 1/DNS/Brand Medically necessary/NS for medications with available generics. Check local state requirements.
 - c. Resources for generic, and some brand-name, medications include:
 - i. www.goodrx.com: Offers reduced pricing on medications, not using insurance, on select medications at specific pharmacies. An online application is available. Of note, GoodRx collects data from users, but recently users can have their data

deleted from GoodRx by completing the following form found at:

<https://www.goodrx.com/blog/goodrx-data-privacy/>

- ii. Foundation funds - Covered below
- d. Several companies are trying to develop all electronic prescription assistance program options but these are not in place yet. Several companies have acknowledged that they are aware of issues related to this now and will work with the provider and patient to develop a solution. Doximity application may assist with HIPAA protected fax needs.
- e. Needymeds.org is a great resource to find collated patient assistance programs that are currently available as well as some forms. Additionally, some common transplant-related resources are collated below:

Medication	Company	Program Types	Resource
Astagraf XL (tacrolimus XL)	Astellas	Copay Card	Astellas Cares
Cellcept (mycophenolate mofetil)	Genentech	Copay Card, Patient Assistance	Patient Assistance for CellCept® (mycophenolate mofetil)
Cresemba (isavuconazole)	Astellas	Copay Card, Patient Assistance	CRESEMBA Support Solutions
Gengraf (cyclosporine modified)	AbbVie	Patient Assistance	https://www.abbvie.com/patients/patient-assistance/program-qualification.html
Envarsus XR (tacrolimus XR)	Veloxis	Copay Card, Patient Assistance	https://www.envarsusxr.com/hcp/patient-support/patient-financial-support/
Harvoni (ledipasvir and sofosbuvir)	Gilead	Copay Card, Patient Assistance	Gilead Advancing Access® program
Mayvret (glecaprevir and pibrentasivir)	AbbVie	Patient Assistance	Program Qualification - Patient Assistance - Patients
Mepron (atovaquone)	GSK	Patient Assistance	GSK for you
Myfortic (mycophenolic acid)	Novartis	Copay Card, Patient Assistance	Novartis Reimbursement Hotline for 30 day voucher and copay cards: 877 952 1000. https://www.copay.novartispharm.com/nvscopay/?#
Neoral (cyclosporine modified) and Sandimmune (cyclosporine)	Novartis		

non-modified)			assistance/patient-assistance-foundation-enrollment ; Phone: 800-277-225.
Noxafil (posaconazole)	Merck	Patient Assistance	Patient assistance application
Nulojix (belatacept)	Bristol Myers Squibb	Copay Card, Patient Assistance	Link to various financial assistance options 1800-861-0048
Prograf (tacrolimus)	Astellas	Copay Card	(tacrolimus) Savings
Rapamune (sirolimus)	Pfizer	Patient Assistance	Pfizer RxPathways: Find Prescription Assistance
Sporanox (itraconazole)	Johnson & Johnson	Patient Assistance	Johnson & Johnson Patient Assistance Program
Valcyte (valganciclovir)	Genentech	Patient Assistance	GENENTECH, INC Patient Assist Program
Various medications	GoodRx	Price comparison resource, Coupon card	GoodRx provides discounted cash pricing at dispensing pharmacies; prices vary based on state and pharmacy Mobile app is available
Vfend (voriconazole)	Pfizer	Patient Assistance	Pfizer RxPathways
Vosevi (sofosbuvir / velpatasvir / voxilaprevir)	Gilead	Copay Card, Patient Assistance	\$5 copay card Gilead Advancing Access® program
Zortress (everolimus)	Novartis	Copay Card, Patient Assistance	Novartis Reimbursement Hotline for 30 day voucher and copay cards: 877 952 1000. https://www.copay.novartispharma.com/nvscopay/?# Foundation for PAP: https://www.novartis.us/our-products/patient-assistance/patient-assistance-foundation-enrollment ; Phone: 800-277-2254

- f. What about foundation support?
- i. [Healthwell](#) has opened a new fund to assist individuals who are at risk or have been quarantined due to COVID-19. Through this unique fund, HealthWell will provide up to \$250 in financial assistance for a 12-month grant period to eligible

patients who have annual household incomes up to 500 percent of the federal poverty level. Grants awarded through the fund will provide reimbursement assistance for *delivered* food and medication and transportation costs to manage COVID-19, while maintaining social distancing protocols, including drive-through testing, delivery of test kits and future treatments. In addition, eligible copayment and incidental costs associated with tele-health treatments and diagnostics related to COVID-19 will also be covered under the fund.

- ii. [Good days®](#) is an independent 501(c)(3) non-profit organization that provides support and assistance for Hepatitis C treatments. Currently, the program is open to enrollment and provides assistance in the amount of \$15,000 for eligible patients. If approved for an open fund, Good Days will provide financial assistance for the full calendar year, or until funds are exhausted.
- iii. [American Kidney Fund](#) Coronavirus Emergency Fund
Due to incredible demand for Coronavirus Emergency Fund Assistance, as of March 25, 2020, funds are depleted and have temporarily stopped. However, the organization is actively seeking for additional sources of funding so that it can be reopened quickly.
- g. What if we need an emergency supply?
 - i. Veloxis and Novartis offer 30 day free or bridge programs. Use contact information above for the respective assistance program.

Drug Shortages:

- 1. What are the current drug shortages?

Drug shortages are ever changing and this pandemic may result in additional shortages for multiple reasons. Updated drug shortage information can be found at:

<https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

<https://www.ashp.org/drug-shortages/current-shortages>

Please refer to this link for previous guidance from the American Society of Transplantation Pharmacy and Pediatric Communities of Practice on generic tacrolimus which still apply to date:

<https://www.myast.org/txpharm-and-pcop-issue-statement-tacrolimus-shortage>. The following tables includes a list of current drug shortages obtained via the American Society of Health Systems Pharmacists Content as of 3/24/2020:

1. Immunosuppressants Used in Solid Organ Transplantation

Generic Name	Companies Affected	Shortage Status	Revision Date	Companies that still have supply
Tacrolimus capsules (0.5, 1, and 5 mg)	Accord, Biopharma, Major, Sandoz	Current	March 04, 2020	Mylan, Strides Pharma, Dr. Reddy's, brand name Prograf from Astellas
Tacrolimus extended-release capsules and tablets	Astellas (only Astagraf XL)	Current	February 07, 2020	Veloxis (Envarsus XR) supply unaffected

Tacrolimus injection	Astellas	Current	March 17, 2020	No other company makes IV Tacrolimus
Mycophenolate mofetil capsules and tablets	Ascend, Hikma, Sandoz	Current	February 25, 2020	Brand name Cellcept from Genentech, Mylan

***As of 03/24/2020 – No current shortages reported for mycophenolic acid (Myfortic), sirolimus, everolimus, belatacept

***Sandimmune/Neoral blister pack recall is related to failure of child-proof packaging. Patients do NOT need to send the medication back and can continue to use the medication as directed. Patients should immediately secure the product out of the sight and reach of children and contact the firm to request a free child-resistant pouch to store the blister package medications. Novartis toll-free at 866-629-6182 from 8 a.m. to 8 p.m. ET daily, email at Novartis5060@stericycle.com or online at www.pharma.us.novartis.com and in the top navigation of the page go to the News tab and click on Statements, or visit <https://www.pharma.us.novartis.com/news/statements/corrective-action-certain-100-mg-sandimmune-and-neoral-blister-packages-us> for more information.

2. Miscellaneous Transplant Associated Medications

Generic Name	Companies Affected	Shortage Status	Revision Date	Companies that still have supply
Acyclovir injection	Auromedics, Fresenius Kabi	Current	March 23, 2020	10 mL and 20 mL vial sizes may be available from affected companies
Cefazolin injection	B.Braun, Baxter, Hikma, Pfizer, Sagent, WG Critical Care	Current	March 04, 2020	Apotex, Fresenius Kabi, Samson Medical Technologies, Sandoz
Fluconazole injection	Renaissance Lakewood Pharmaceuticals	Current	January 22, 2020	Pfizer, Sagent, Baxter
Leucovorin injection	Hikma, Sagent	Current	March 14, 2020	Teva, Fresenius Kabi, Mylan
Pantoprazole injection	Auromedics, Hikma, Pfizer	Current	March 13, 2020	Sun Pharma
Pentamidine injection and inhalation	Fresenius Kabi and Seton	Current	March 16, 2020	Fresenius Kabi and Seton
Vancomycin injection	Auromedics, Pfizer,	Current	March 17,	Alvogen,

	Baxter, Sagent		2020	Athenex, Fresenius Kabi, Mylan, Xellia, Samson Medical Technologies
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***As of 03/24/2020 – No current shortages reported on atorvastatin, atovaquone, dapson, ganciclovir injection, sulfamethoxazole/trimethoprim, lopinavir/ritonavir, nystatin suspension, oseltamivir, sulfamethoxazole/trimethoprim, tocilizumab, valganciclovir, voriconazole

2. What are current recommendations and availability for COVID-19 associated medications?
 - a. The CDC has published guidance that can be found at: [Information for Clinicians on Therapeutic Options for COVID-19 Patients](#)
 - b. A recent review outlines options for COVID-19 Treatment: COVID-19 Treatment: A Review of Early and Emerging Options Erin K McCreary, PharmD, BCPS, BCIDP, Jason M Pogue, PharmD, BCPS, BCIDP et al. In Open Forum Infectious Disease: Open Forum Infectious Diseases, <https://doi.org/10.1093/ofid/ofaa105>
 - c. Shortages affecting these medications include:

Generic Name	Companies Affected	Shortage Status	Revision Date	Companies that still have supply
Albuterol sulfate MDI	Teva, Prasco, GSK	Current	March 23, 2020	Merck, Par
Azithromycin IV	Pfizer, Apotex, Auromedics, Sun Pharma, Fresenius Kabi	Current	March 23, 2020	Slate Run Pharmaceuticals,
Hydroxychloroquine sulfate tablet	Amneal, Major, Mylan, Teva,	Current	March 19, 2020	Concordia, Sandoz, Zydus, Prasco
Chloroquine Phosphate Tablet	Rising Pharmaceuticals, Sun Pharma	Current	March 20, 2020	none

*****States are enacting 14-day supply restrictions on hydroxychloroquine, as well as limiting to FDA approved indications or confirmed positive COVID-19 cases. Please visit your respective state board of pharmacy’s website for specific stipulations with regards to COVID-19.**

*****No pharmacist should dispense hydroxychloroquine or chloroquine except when prescribed for an FDA-approved indication or as approved by their state for COVID.**
<https://www.ama-assn.org/press-center/ama-statements/ama-apha-ashp-issue-joint-statement-about-covid-19-medications>

- d. There are several investigational agents including, but not limited to:
 - 1. Remdesivir
 - a. Gilead setting up Expanded Access Programs
<https://www.gilead.com/purpose/advancing-global-health/covid-19/emergency-access-to-remdesivir-outside-of-clinical-trials>
 - b. Remdesivir be available via compassionate use/clinical trial only for those who meet certain criteria and possibly only pregnant and pediatric patients as of 3/24/2020
 - c. To start the request for remdesivir through Gilead's expanded access program visit: <https://rdvcu.gilead.com/>
 - i. In order to access remdesivir, a number of documents must be completed and submitted to the manufacturer
 - d. The following documents are required and may be prepared in advance to expedite the ordering process for individual patients:
 - i. Signing of a Confidential Disclosure Agreement
 - ii. Signing of Prescriber Agreement
 - iii. Communication from Hospital CEO or Ethics Committee to approve the use of a Compassionate Access Medicine in the hospital
 - 2. For additional information on ongoing COVID-19 trials refer to: <https://clinicaltrials.gov/ct2/results?cond=COVID19&term=&cntry=&state=&city=&dist>
 - a. Of note, some ongoing trials exclude patients on immunosuppressive therapies
- e. Inhaled medications
 - 1. Given the potential for spread via aerosolization of COVID-19 with the use of nebulizers, metered dose inhalers (MDIs) should be used for all COVID-19 rule-out and confirmed cases
 - a. Ipratropium should be restricted to suspected or confirmed COVID-19 patients with concomitant COPD
 - b. Recommend use of albuterol nebulizers for non-COVID patients to conserve supply of MDIs

Additional Information

- 1. Are there concerns with transmission of the virus via food or packages?
<https://www.fda.gov/food/food-safety-during-emergencies/food-safety-and-coronavirus-disease-2019-covid-19>
<https://www.cdc.gov/coronavirus/2019-ncov/prepare/prevention.html>

There is likely very low risk of spread from products or packaging that are shipped over a period of days or weeks at ambient temperature. Currently, there is no evidence to support transmission of COVID-19 associated with imported goods, including food and drugs for humans and pets. Coronaviruses are generally thought to be spread from person-to-person through respiratory droplets.

- 2. Are angiotensin-converting enzyme inhibitors (ACE-I) and angiotensin receptor blockers (ARBs) safe during the COVID-19 pandemic?

- a. "The Council on Hypertension of the European Society of Cardiology wish to highlight the lack of any evidence supporting harmful effect of ACEi and ARB in the context of the pandemic COVID-19 outbreak. The Council on Hypertension strongly recommends that physicians and patients should continue treatment with their usual anti-hypertensive therapy because there is no clinical or scientific evidence to suggest that treatment with ACEi or ARBs should be discontinued because of the Covid-19 infection."
 - b. European Society of Cardiology- [Position Statement of the ESC Council on Hypertension on ACE-Inhibitors and Angiotensin Receptor Blockers](#)
 - c. American College of Cardiology: <https://www.acc.org/~media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/2020/02/S20028-ACC-Clinical-Bulletin-Coronavirus.pdf>
3. Are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) safe to take during the COVID-19 pandemic?

- a. Acetaminophen is recommended for treatment of fevers. FDA is aware of news reports stating the use of non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, could worsen coronavirus disease (COVID-19). These news reports followed a March 11, 2020, letter in *The Lancet medical journal*, which hypothesized that an enzyme (a molecule that aids a biochemical reaction in the body) is increased by NSAIDs and could aggravate COVID-19 symptoms. At this time, FDA is not aware of scientific evidence connecting the use of NSAIDs, like ibuprofen, with worsening COVID-19 symptoms. The agency is investigating this issue further and will communicate publicly when more information is available.

<https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-patients-use-non-steroidal-anti-inflammatory-drugs-nsaids-covid-19>

4. Are there at home laboratory testing options for transplant recipients?

- Some regions and centers (University of Washington in Seattle) may have the availability to do at home tacrolimus testing. Where possible, this may be a good strategy to manage currently outpatient and stable transplant recipients. Where home testing is not possible, optimizing the use of local laboratories versus coming into busy and potentially contaminated academic medical centers is advised.
- CareDx is now offering RemoTraC, a service to provide at-home blood draws for transplant patients. RemoTraC includes AlloSure and AlloMap, CareDx's surveillance tests, along with a panel of routine tests. RemoTraC will allow you to continue with your regular testing schedule while avoiding in-person visits to a hospital or lab during the COVID-19 pandemic.
 - <https://xynmanagement.secure.force.com/RemoTraC/>