

# **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.
  - i. Patients may contact the dispensing pharmacy or insurance plan and ask about the ability to fill a 90-day supply of medications.
    1. Ability to obtain 90-day supply is dependent on insurance plan, dispensing pharmacy, state law, and specific medications.
      - a. Medicare Part B: historically limited to 30-day supplies.
      - b. Medicare Advantage plans and certain Medicaid programs: some reports of success with extended fill supplies.
      - c. Insurance may require a specific mail order pharmacy for 90-day supply.
    2. Limited stability of compounded medications and commercially available liquids may prevent dispensing of 90-day supplies.
  - ii. Patients should contact the prescriber for a 90-day supply prescription, if eligible.
  - iii. If patients are unable to get a 90-day supply, they may still be eligible for early refills of the 30-day supply.
- b. Advise patients to contact the transplant clinic if they have difficulty obtaining medications or have questions after calling the pharmacy or insurance plan.
- c. Requests for extended supplies of medications should be limited to patients on stable or established doses.
- d. Requests for extended supplies of medications must be balanced with risk of potential drug shortages.

### **2. Have state governments taken any actions pertaining to prescription medication access and supply?**

- a. Yes, use this link for state-specific actions: [State-Specific Actions on Medication Access](#)

### **3. Have any of the state Medicaid programs made adjustments because of COVID-19?**

- a. Yes, use this link for state-specific adjustments: [State-Specific Medicaid Adjustments](#)

### **4. Have there been issues with early refill requests?**

- a. Payers may or may not allow members to obtain early refills due to COVID-19
- b. Some pharmacy corporations may have internal rules or regulations limiting early refills
- c. 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 and there is not a pharmacy corporate rule preventing you from doing so, 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. Documentation of the reasons for the override should be noted on the prescription or in a log. 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.

- d. Contact information and override codes for several insurance companies can be found here: [Pharmacy Overrides: Insurance Override Codes](#)

**5. 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
- f. Of note, pharmacies must follow federal and state pharmacy laws, insurance company stipulations, and corporate rules and regulations. Due to variation, this may impact available options.
  - i. Signature requirements upon prescription receipt may still apply depending on federal and state laws. This should be anticipated and patients can be advised to use their own pen and/or gloves if desired. In addition they should be advised to wash their hands with soap and water for 20 seconds after signing/accepting deliveries. If soap and water are not available, use of a hand sanitizer with at least 60% alcohol is recommended.
  - ii. Patients can check with their respective pharmacist or pharmacy manager regarding options to enhance social distancing. If patients are not comfortable with the services a pharmacy is providing, they have the option of transferring prescriptions elsewhere as allowed by insurance.
  - iii. Using a local transplant specialty pharmacy can be considered as they may be more attuned to the unique needs of a transplant recipient and transplant family.

**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 are often available for specialty medications to be filled at local retail pharmacies, if urgently needed
- b. Some mail-order pharmacies are offering same day courier services

**6. How should transplant teams handle loss of transplant patient employment?**

- a. Involve social work to help navigate government assistance/insurance
- b. Be aware of emergency enrollment periods for state health exchanges
- c. If available, consider patient enrollment in state-specific discounted health care service programs for low-income individuals and families
- d. See below for information on patient assistance programs to assist with emergency supplies between coverage gaps as well as other resources to decrease cost of prescription medications including discount programs and foundation funds

**7. What are the available resources for discount coupons, patient assistance programs, and copay cards?**

- a. PhPRMA's Medicine Assistance Tool (MAT) (<https://mat.org/>) is 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.
- b. [Needymeds.org](http://Needymeds.org) is a great resource to find collated patient assistance programs that are currently available as well as some forms.
- c. Discounted pricing coupons for generic, and some brand-name, medications include:
  - i. [www.goodrx.com](http://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/>
- d. Many resources are available for brand-name products through the pharmaceutical manufacturers
  - i. Copay Cards: Help cover a portion of patients' out-of-pocket expenses up to an annual limit. Copay cards can only be used with commercial insurance if the prescription costs are partially covered by the insurance plan (i.e., patients 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
- e. Patients may require new prescriptions for many patient assistance programs and copay card programs that designate Brand Medically Necessary/NS/DAW 1/DNS for medications with available generics. Check local state requirements.
- f. 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.
- g. Some common transplant-related resources are collated below:

Medication	Company	Program Types	Resource
Astagraf XL (tacrolimus XL)	Astellas	Copay Card	<a href="#">Astellas Cares</a>
Cellcept (mycophenolate mofetil)	Genentech	Copay Card, Patient Assistance	<a href="#">Patient Assistance for CellCept® (mycophenolate mofetil)</a>

Cresemba (isavuconazole)	Astellas	Copay Card, Patient Assistance	<a href="#">CRESEMBA Support Solutions</a>
Gengraf (cyclosporine modified)	AbbVie	Patient Assistance	<a href="#">myAbbVie Assist</a>
Envarsus XR (tacrolimus XR)	Veloxis	Copay Card, Patient Assistance	<a href="#">Veloxis Financial Support</a>
Epclusa (sofosbuvir and velpatasvir)	Gilead	Copay Card, Patient Assistance	<a href="#">Gilead Support Path Program</a>
Harvoni (ledipasvir and sofosbuvir)	Gilead	Copay Card, Patient Assistance	<a href="#">Gilead Support Path Program</a>
Insulins			
Humalog (insulin lispro): U-100, U-200, 50/50,75/25, Insulin lispro U-100, Humulin N (NPH), Humulin R (regular insulin) U-100, Humulin 70/30 (NPH/regular) Basaglar (insulin glargine)	Eli Lilly	Copay Card	<a href="#">Lilly Insulin Value Program</a> Solution Center: 1-833-808- 1234 [assistance with Baqsimi (glucagon) nasal powder 3 mg is also provided via Solution Center]
Humulin R U-500 (regular insulin)	Eli Lilly	Copay Card	<a href="#">Humulin® R U-500 Savings Card</a>
Novolog (insulin aspart) U-100, Fiasp (insulin aspart) U-100, Novolog Mix 70/30 (NPH/regular), Levemir (insulin detemir),	Novo Nordisk	Copay Card	<a href="#">Novocare.com</a>

Tresiba (insulin degludec) U-100, U-200, Xultophy (insulin degludec/liraglutide) 100/3.6			
Novolin N (NPH) Novolin R (regular)	Novo Nordisk	Novo Nordisk Savings Card & Patient Assistance Program	<a href="#">NovoMedLink Savings Card for all Novo Nordisk diabetes products</a>
Admelog (insulin lispro) vials and SoloStar	Sanofi-aventis	Savings Program	<a href="#">Insulins Val-you Savings Program</a>
Apidra (insulin glulisine) vials and SoloStar	Sanofi-aventis	Copay Card	<a href="#">Apidra Co-Pay Offer</a>
Lantus (insulin glargine) vials and Solostar	Sanofi-aventis	Copay Card, Patient Assistance	<a href="#">Lantus Copay Savings &amp; Diabetes Support</a>
Toujeo (insulin glargine) U-300	Sanofi-aventis	Copay Card, Patient Assistance	<a href="#">Toujeo Copay Savings &amp; Diabetes Support</a>
Afrezza (inhalation powder)	MannKind	Copay Card	<a href="#">Afrezza Savings Program</a>
Mayvret (glecaprevir and pibrentasivir)	AbbVie	Patient Assistance	<a href="#">Program Qualification - Patient Assistance - Patients</a>
Mepron (atovaquone)	GSK	Patient Assistance	<a href="#">GSK for you</a>
Myfortic (mycophenolic acid)	Novartis	Copay Card, Patient Assistance	<a href="#">Patient Savings Co-Pay Card and 30 day Free Trial Voucher</a>
Neoral (cyclosporine modified) and Sandimmune (cyclosporine non-modified)	Novartis		Foundation for PAP: <a href="https://www.novartis.us/our-products/patient-assistance/patient-assistance-foundation-enrollment">https://www.novartis.us/our-products/patient-assistance/patient-assistance-foundation-enrollment</a> Phone: 1-800-277-2254.

Zortress (everolimus)	Novartis	Copay Card, Patient Assistance	<a href="#">Patient Savings Co-Pay Card and 30 day Free Trial Voucher</a>  Foundation for PAP: <a href="https://www.novartis.us/our-products/patient-assistance/patient-assistance-foundation-enrollment">https://www.novartis.us/our-products/patient-assistance/patient-assistance-foundation-enrollment</a> Phone: 1-800-277-2254.
Noxafil (posaconazole)	Merck	Patient Assistance	<a href="#">Merck Helps Patient Assistance Program Application</a>
Nulojix (belatacept)	Bristol Myers Squibb	Copay Card, Patient Assistance	<a href="#">BMS Access Support for various financial assistance options</a> 1-800-861-0048
Prevymis (letermovir)	Merck	Copay Card, Patient Assistance	<a href="#">Merck Access Program</a>
Prograf (tacrolimus)	Astellas	Copay Card	<a href="#">Prograf Co-Pay Card</a>
Rapamune (sirolimus)	Pfizer	Patient Assistance	<a href="#">Pfizer RxPathways: Find Prescription Assistance</a>
Sporanox (itraconazole)	Johnson & Johnson	Patient Assistance	<a href="#">Johnson &amp; Johnson Patient Assistance Program</a>
Tolsura (itraconazole)	Mayne Pharma	Copay Card	<a href="#">Mayne Pharma Patient Savings Card</a>
Valcyte (valganciclovir)	Genentech	Copay Card, Patient Assistance	<a href="#">Valcyte Co-Pay Card</a>  <a href="#">Genentech Access to Care Foundation- Transplants</a> 1-888-754-7651
Various medications	GoodRx	Price comparison resource, Coupon card	<a href="#">GoodRx</a> provides discounted cash pricing at dispensing pharmacies; prices vary based on state and pharmacy

			Mobile app is available
Vfend (voriconazole)	Pfizer	Patient Assistance	<a href="#">Pfizer RxPathways</a>
Vosevi (sofosbuvir / velpatasvir / voxilaprevir)	Gilead	Copay Card, Patient Assistance	<a href="#">Gilead Support Path Program</a> <a href="#">Vosevi Co-Pay Card Registration</a>

**8. What foundation support is available to help transplant patients who are in need of assistance?**

- a. [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.
- b. [Good days](#)<sup>®</sup> 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.
- c. [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. American Kidney Fund is also looking for independent donors. Donations can be made on the Emergency Fund website.

**9. What options are available for patients who are in need of an emergency supply of medications without insurance coverage?**

- a. Veloxis and Novartis offer 30-day free or bridge programs. Use contact information above for the respective assistance program.
- b. Bristol Myers Squibb expanded its current program to include patients who lose their insurance due to the COVID-19 pandemic and will provide access to free branded medication.

**Drug Shortages:**

**1. What are the current drug shortages that may impact transplant patients?**

- a. 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>  
<https://www.ashp.org/drug-shortages/current-shortages>
- b. Please refer to the previous guidance from the American Society of Transplantation Pharmacy and Pediatric Communities of Practice on generic tacrolimus which still apply to date at: <https://www.myast.org/txpharm-and-pcop-issue-statement>
- c. The following tables ([COVID-related Drug Shortages](#)) includes a list of current drug shortages obtained via the American Society of Health Systems Pharmacists Content as of 4/9/2020. Companies affected may still have supply of certain strengths or package sizes.
- d. **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, Mylan	Current	April 6, 2020	Brand name Cellcept from Genentech, Accord

\*\*\*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](mailto: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>.

**e. What are current recommendations and availability for COVID-19 associated medications?**

- i. The CDC has published guidance that can be found at: [Information for Clinicians on Therapeutic Options for COVID-19 Patients](#)
- ii. The Infectious Disease Society of America has published guidance that can be found at: [Guidelines on the Treatment and Management of Patients with COVID-19](#)
- iii. The American Society of Health-System Pharmacists (ASHP) has published guidance that can be found at: [Assessment of Evidence for COVID-19 Related Treatments](#)
- iv. Shortages affecting these medications include:

Generic Name	Companies Affected	Shortage Status	Revision Date	Companies that still have supply
Albuterol sulfate MDI	Teva, Par, Prasco, GSK	Current	March 24, 2020	Merck
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 24, 2020	Concordia, Sandoz, Zydus, Prasco
Chloroquine Phosphate Tablet	Rising Pharmaceuticals, Sun Pharma	Current	March 24, 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>

**f. There are several investigational agents including, but not limited to:**

- i. Remdesivir
  1. Available through clinical trials:
    - a. [NCT04280705](#)

- b. [NCT04292730](#)
  - c. [NCT04292899](#)
  - d. [2020-000936-23](#)
2. Emergency access outside of clinical trials:
- a. Gilead has set up an Expanded Access Program: <https://www.gilead.com>, [Expanded Access Treatment Protocol](#)
  - b. Individual compassionate use requests continue to be reviewed for pregnant women and children less than 18 years with confirmed COVID-19 and severe manifestations of disease: <https://rdvcu.gilead.com/>
- ii. For additional information on ongoing COVID-19 trials refer to: <https://clinicaltrials.gov/ct2/results?cond=COVID19>
  - iii. Of note, some ongoing trials exclude patients on immunosuppressive therapies

**g. Inhaled Medications:**

- i. 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
- ii. Ipratropium should be restricted to suspected or confirmed COVID-19 patients with concomitant COPD
- iii. Recommend use of albuterol nebulizers for non-COVID patients to conserve supply of MDIs

**h. Controlled Substances:**

- i. Controlled substances have been in short supply due to increase in mechanically ventilated patients.
- ii. The Drug Enforcement Agency (DEA) has made changes to Annual Production Quotas (APQs) to address these shortages
  - 1. APQs determine the annual quantities of schedule I and II controlled substances that may be manufactured in the United States. This quota system was established by the Controlled Substances Act of 1970 and was enhanced in 2018 in response to the nationwide opioid epidemic.
  - 2. APQs are based on predicted annual needs to provide adequate quantities for the estimated medical, scientific, research, and industrial needs of the United States market, for lawful exports, and to establish reserve stocks. All APQs and assessments of annual needs are subject to adjustment based on DEA Codes of Federal Regulations.
  - 3. On April 7, 2020, the DEA adjusted the 2020 APQs to provide for the increased estimated needs. (<https://www.dea.gov>). Under this order, the DEA committed to monitoring manufacturing and procurement quotas to ensure that the increases in APQs will be utilized primarily to manufacture medications involved in sedation, intubation, and pain relief for patients being treated for COVID-19 to ensure an uninterrupted supply during the public health emergency.

4. APQs may be updated as needs are identified. All APQ adjustments will be published by the DEA in the Federal Register general notices (<https://www.federalregister.gov>).

#### **Additional Information**

##### **1. Are there concerns with transmission of the virus via food or packages?**

- a. 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.

- i. <https://www.fda.gov/food/food-safety-during-emergencies/food-safety-and-coronavirus-disease-2019-covid-19>

- ii. <https://www.cdc.gov/coronavirus/2019-ncov/prepare/prevention.html>

##### **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.”

- i. European Society of Cardiology- [Position Statement of the ESC Council on Hypertension on ACE-Inhibitors and Angiotensin Receptor Blockers](#)

- b. 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.

- i. <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?**

- a. Some regions and centers (e.g. - 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.

- b. CareDx is 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. More information can be obtained from:

- <https://xynmanagement.secure.force.com/RemoTraC/>

- c. Eurofins Viracor's Labs@HOME is an in-home blood draw service offering the option to order routine infectious disease and transplant-related testing and Viracor's [TRAC™](#) (Transplant Rejection Allograft Check). Eurofins Transplant Genomics offers a similar service to collect samples for TruGraf blood tests and standard labs. More information can be obtained via email at [info@viracor-eurofins.com](mailto:info@viracor-eurofins.com) or <https://trugraf.com/>
- d. Natera's ProReach Program utilizes their nationwide mobile phlebotomy network to draw both Prospera transplant assessment test and routine labs remotely. Providers can customize how to follow transplant patients with a dedicated Natera clinical concierge team. More information can be obtained from: <https://www.natera.com/organ-transplant/proreach-program>

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