



The goal of the Centers for Medicare and Medicaid Services (CMS) ruling that permits home infusion, is to provide safe access to care with as little disruption possible to the Alpha-1 patient. We are in a Public Health Emergency (PHE) during the COVID-19 pandemic and these rules were put into place to protect you and to make sure your medication is available to you.

Some of the questions posed from our community members require individual case management and exceed our policy work in this area. If you need case management, the Foundation recommends that you discuss administration of your drug and billing with your health care provider. You should also discuss with your provider what the cost to you will be.

For most patients already on Medicare Part B who have a supplemental policy (Medigap); Part B home infusions will require the physician or hospital to order the drug and have a home health nurse deliver and administer it. The amount you are billed by Part B should not change. If you do not receive infusions under Part D and are switched to Part D you will have to pay into Medicare plan up to \$6,300 which then puts you into the catastrophic level where you will not have any additional cost sharing. Assistance is available thru Patient Assistance Programs (PAP). If you are already receiving infusions under Medicare Part D you may have already met your catastrophic amount and may not have any additional cost sharing.

Frequently Asked Questions:

Q: Why can Homebound Home Health Agency only bill Part D, and not Part B?

A: Part B is a physician administered benefit. The CMS rule expanded the definition of Homebound which is a Part D benefit and not a Part B benefit.

Q: Would it require a medical criteria review to changing from part B or D?

A: A new prescription may be required which may trigger the need for prior authorization.

Q: Are the Alpha-1 patients on Medicare being sent the new guidelines, so that they can make an informed decision?

A: Medicare is not distributing the new guidelines to individual beneficiaries as this is a policy change. This is the reason that the Alpha-1 Foundation continues to reach out and educate our community (link to fact sheet).

Q: For patients who like going to their infusion centers, will there be any issues switching back to their infusion center after the pandemic?

A: When COVID-19 is no longer a pandemic and therefore no longer a PHE we would expect all things to go back to the way they were prior to the pandemic. However, we can expect to see guidelines for social distancing and wearing Personal Protective Equipment (PPE).

Q: What does the infusion center where the patient is currently infusing need to do to make the change to home infusion?

A: They should be working to assist you and to be sure you are safe.

Q: If there are additional reviews involved with a patient moving from the infusion facility to home, could there be any risks with continuation of therapy?

A: There should not be.

Q: As an Alpha-1 nurse working on the front line, one on one with patients, what should I be doing to help with this?

A: Wear PPE and review the Alpha-1 Foundation Fact Sheets. ([link](#))

Q: Is there any hope for self-infusions to be covered by Medicare in the future?

A: There are some limitations with self-infusions because only one product has approval by the FDA to be included in the product label. If a clinical trial was conducted and the FDA approved labeling for all augmentation therapies an appeal could be made to CMS for coverage.

Q: If a provider who has someone infusing in a clinic or facility are willing to have them trained for self- infusion in the home, would that be paid for my Medicare Part B and supplemental plan?

A: Only the drug would be paid for and someone would have to bring the drug from the clinic or facility to the patient.

Q: Can one self-infuse at home under Part B?

A: Part B is a physician administered benefit. Medicare **Part B** covers **drugs** that are **administered** by infusion or injection in **physician** offices and hospital outpatient departments. However, If the distributor has a pharmacy license the drug can be shipped directly to your home for self- infusion. Self-administration should be listed on the label and supervised by a physician telehealth consult.

Q: Can these changes be made permanent after the COVID-19 crises is over?

A: These changes would have a greater chance of being made permanent if administered under Medicare Part B; because the change to Part D is an expansion of the definition of homebound to include individuals who are listed as high-risk during the PHE.

Q: Once the state of emergency is over, will patients need a new prescription to go back to infusions at a facility or will they revert back automatically?

A: Unknown

Q: Who is the home health care provider?

A: Diplomat Specialty Pharmacy, Coram, Accredo or Eversana.

Q: Will the bill be directly sent to Medicare by whoever is doing the infusions?

A: Yes, under Part B physician's contract with nursing and bill Medicare.

Q: If a Specialty Pharmacy nurse bills Medicare and if they have part A, part B, part D and a supplement, would the supplement pick up the rest?

A: Specialty pharmacy billing under Part D should be administered as if the individual is homebound; therefore supplemental coverage should kick in.

Q: If someone is now going to a hospital with Part B and supplement, and doesn't have Part D; will they be required to purchase a prescription Part D plan, and then have to apply for financial aid to cover the copay, and premium?

A: Part B should be utilized and should not require a switch to Part D.

Q: Are they going to relax the criteria for "homebound" status., and enable billing to go through Part B and allow home health to bill for nursing and supplies? And then would the Pharmacies bill Medicare directly for the drug?

A: Homebound status applies to Part D. Home Health can bill for nursing and supplies under Part D.

If an individual is homebound and home nursing is provided the specialty pharmacy would bill.

Q: Who will decide when it is 'safe' for Alpha 1 patient to return to a facility for infusions?

A: The Federal government has not offered clear guidance and has left this determination up to the States. The Alpha-1 Foundation continues to recommend shelter in place for individuals with Alpha-1.

Q: Will the home infusions exception be allowed to remain in place for longer time frame-well after COVID-19 is considered to be under control for the general population?

A: We assume that CMS will leave the guidelines in place and transition them out when all States are no longer under a PHE and when COVID-19 is no longer classified as a pandemic.

Q: Why are HIPAA regulations being relaxed for this period?

A: This is being done to allow for telehealth consultations.

Q: Is the decision to switch up to the patient?

A: Home infusion is a patient choice made in consultation with your healthcare provider.

Q: With COVID 19 still spreading and the data being limited on how long this can continue to be a problem, how long will these services be available?

A: We assume that this will not be a permanent option but one that is phased out slowly.

Q: If Medicare covers supplies and infusions at the infusion center, will they pick up all costs if they infuse at home. I know that Medicare will pay up to what they pay for going to a facility, but will the subscriber be responsible for the balance?

A: Part D expressly permits billing of supplies. Part B does not but it is assumed.

Q: Is there a way to be financially assisted with the home infusions?

A: All available Patient Assistance Programs should help if they have co-pay programs.

Q: Could there be a way to permanently get HIPAA laws to change where they can do TeleHealth calls with their Drs for simple appointments?

A: I am sure that those who promote Telehealth will lobby for a permanent change, but this is not guaranteed, unless it is done administratively by CMS or legislatively by Congress.

Q: Will the home care nurses have access to N95 masks and gloves?

A: Personal Protective Equipment is recommended by the Alpha-1 Foundation and the responsibility of those administering the services.

Q: Should patients skip infusions to keep their exposure down at their infusion center because they can't afford home infusions?

A: The Alpha-1 Foundation has recommended that patients continue to receive their infusions on the same schedule as pre -COVID-19.

Q: How long does the process take for a patient to switch over from facility to home with these new guidelines?

A: The new guidelines are intended to be immediate retroactive to March 30, 2020. One would hope that the billing departments of institutions and homecare companies do not delay patient care.

Q: Are Medicare patients being sent this information? Is there a helpline to help guide them into obtaining this process of home infusions?

A: CMS has not done outreach to subscribers to inform them of the temporary change. The Foundation asked for a helpline to be established to answer questions about this temporary rule. This request was made in the Foundation's comment letter on the CMS guidelines. We have not received a response from CMS.