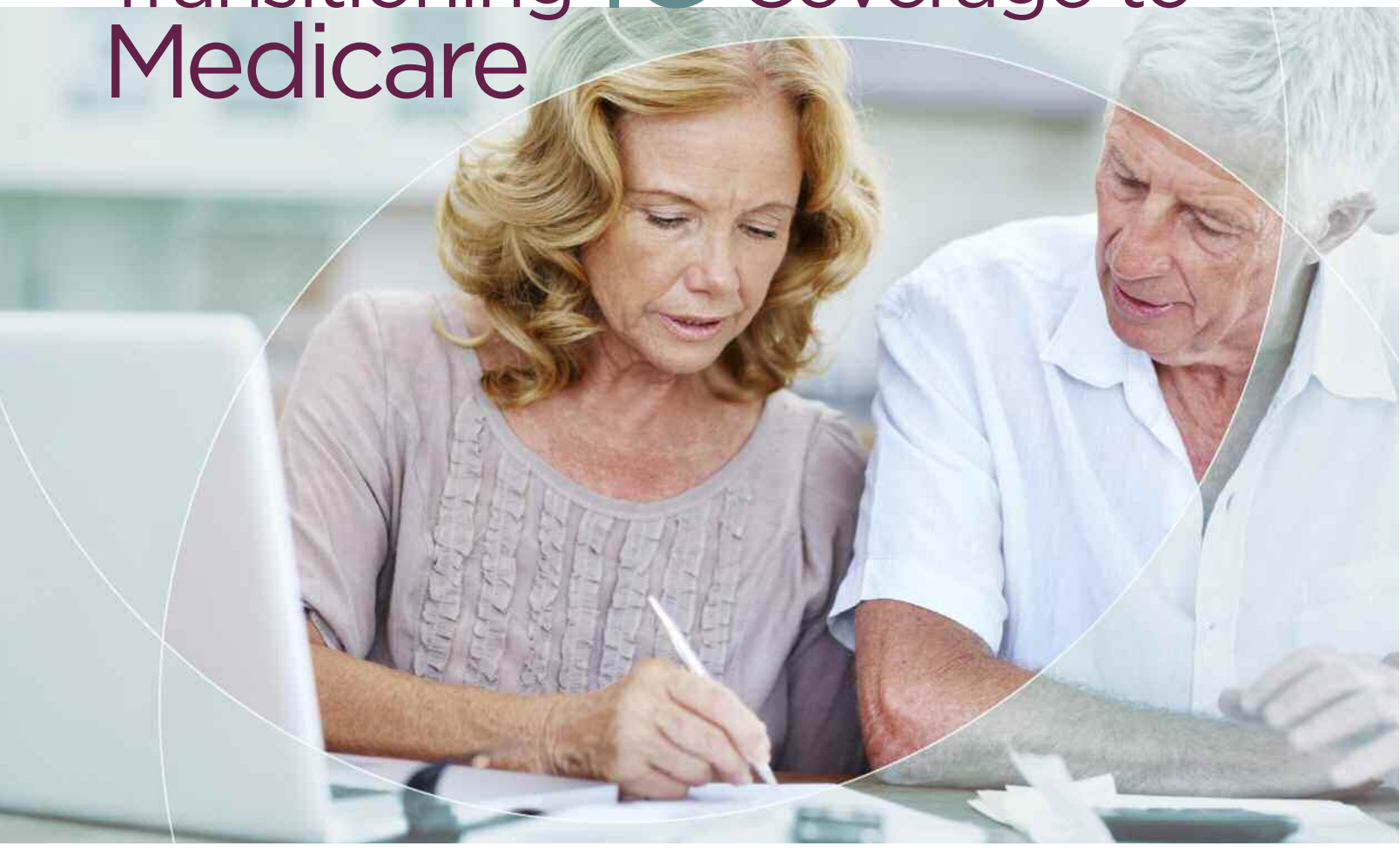
Transitioning IG Coverage to Medicare



Options in Medicare coverage can be more complicated than IG therapy, but these guidelines can help to ensure a smooth transition.

By Michelle Greer, RN, and Leslie Vaughan, RPh

IMMUNE GLOBULIN (IG) is a complex therapy, both clinically and financially, that is used to treat rare and difficult-to-diagnose diseases. For some, IG is a lifetime therapy. And, while at one time this therapy was typically approved and reimbursed without question, today there are extensive medical policies in place that require a diagnosis to be proved and the medical need for IG justified.

Compared with all other insurance plans, Medicare probably varies most in its coverage policies for IG therapy. Therefore, patients who continue to receive IG therapy when they turn 65 or otherwise become eligible for Medicare need to know how to successfully transition to Medicare. In fact, changes in site of care and route of administration may be necessary to ensure therapy is continued without disruption and financial strain.

Applying for Medicare

To be eligible for Medicare coverage, patients must be age 65 or older and eligible for retirement benefits under Social Security, or a federal, state or local government employee. To be eligible for Social Security, individuals must have 40-plus quarters of Social Security-covered employment; receive benefits under a spouse's work record and be currently married; or have received benefits under a former spouse to whom they were married for at least 10 years.

Individuals also may be eligible for Medicare if they are receiving disability benefits under Social Security Disability Insurance; have received railroad retirement benefits for 24 or more months; have end-stage renal disease; or have amyotrophic lateral sclerosis, also known as Lou Gehrig's disease.

Some individuals will be automatically enrolled in Medicare when they turn 65, whereas others will need to apply. Those who are already receiving Social Security benefits and have enough work quarters will automatically be enrolled for Medicare Parts A and B when they turn 65 or on the 25th month of disability. All others will need to apply for Medicare. An individual who needs to apply for Medicare has a seven-month initial enrollment period to sign up for Part A and/or Part B. This initial enrollment period begins three months prior to the individual's 65th birthday month, includes the birthday month and concludes three months after the birthday month. Starting the application process as early as possible can minimize any problems getting enrolled.

One of the most important things to consider when turning 65 is if insurance through an employer will continue. If patients or their spouses are still working and the employer has 20 or more employees, Medicare becomes the secondary insurance until they retire. If patients or their spouses plan to retire, and their employer's insurance will continue, Medicare will become the primary insurance and will cover all approved charges at 80 percent, with the employer's insurance generally covering the remaining 20 percent of approved charges. If the employer's insurance will terminate, patients may consider obtaining a Medicare supplemental plan, since 20 percent of the cost of monthly IG therapy can be financially taxing.

For more detailed information, Medicare has a free booklet titled *Medicare and Other Health Benefits: Your Guide to Who Pays First* that explains all of the options. Another excellent free resource for learning about Medicare is a booklet titled *Medicare and You*. These booklets, as well as more comprehensive information on basic Medicare coverage, including eligibility, coverage criteria and plan options, can be found on the Medicare website at www.Medicare.gov.

Choosing Medicare Benefits

The original Medicare plans include Medicare Parts A and B. There also is Medicare Part D (the Medicare prescription drug plan) for which patients can sign up. An alternative option to Parts A and B is Medicare Part C (the Medicare Advantage Plan), which is similar to an HMO and usually includes prescription drug coverage.

Coverage for IG varies based on patients' diagnosis, where they currently receive therapy and whether they receive therapy via the intravenous (IVIG) or subcutaneous (SCIG) route.

Drug coverage for an immune deficiency diagnosis. IG therapy for an immune deficiency is 80 percent covered under Medicare Part B. This is the case whether patients receive IVIG or SCIG. However, any coverage changes should be confirmed for the site of therapy, including the hospital, physician office or home. There is broader coverage in the hospital and physician office than there is in the home. In the homecare setting, coverage is limited to 14 specific diagnosis codes:

- D80.0: Hereditary hypogammaglobulinemia
- D80.5: Immunodeficiency with increased immunoglobulin M [IgM]
- D83.0: Common variable immunodeficiency with predominant abnormalities of B cell numbers and function
- D83.2: Common variable immunodeficiency with autoantibodies to B or T cells
- D83.8: Other common variable immunodeficiencies
- D83.9: Common variable immunodeficiency, unspecified
- D82.0: Wiskott-Aldrich syndrome
- D81.0: Severe combined immunodeficiency with reticular dysgenesis
- D81.1: Severe combined immunodeficiency with low T and B cell numbers
- D81.2: Severe combined immunodeficiency with low or normal B cell numbers
- D81.6: Major histocompatibility complex class I deficiency
- D81.7: Histocompatibility complex class II deficiency
- D81.89: Other combined immunodeficiencies
- D81.9: Combined immunity deficiency, unspecified

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Patients with an immune deficiency that is not identified by one of these 14 diagnosis codes may be covered under the Part D benefit, which is explained below.

Unfortunately, IG is not reimbursed very well under Medicare Part B. Prior to the passage of the 21st Century Cures Act in December 2016, reimbursement for SCIG received at home was adequate to cover the cost of immune globulin. Now, for most providers, Medicare reimbursement is below their cost to purchase IG.

Patients who receive IVIG in a physician office may be asked to change their site of care to a hospital outpatient setting if continuing to receive IVIG, or to change to a home setting to begin receiving SCIG or IVIG. Medicare publishes a new fee schedule every quarter that may impact the brand of IG patients receive. Based on these quarterly reimbursement rates for IG, providers may ask patients to change brands and/or routes of administration if reimbursement for their current product dips below the cost to acquire it.

There are six SCIG products: Gammagard Liquid (Shire), Gamunex-C (Grifols), Gammaked (Kedrion Biopharma), Hizentra (CSL Behring), HYQVIA (Shire) and Cuvitru (Shire). HYQVIA differs from the others because it is a combination product using IG and hyaluronidase. The hyaluronidase component makes it possible for patients to infuse monthly rather than the more frequent dosing that may be required when using traditional SCIG products. Medicare originally did not allow coverage for HYQVIA in the home setting under the Part B benefit; however, that decision has been partially reversed. The manufacturer of HYQVIA, Shire, recommends a dose ramp-up, which means patients start with a partial dose and increase the dose with each subsequent treatment until they reach a maintenance dose. Currently, coverage under Medicare Part B will not pay for the ramp-up phase in the home. Payment for the ramp-up phase is available only in the hospital outpatient and physician office settings. Once the patient is stabilized with the maintenance dose, Part B will cover ongoing doses in the home setting.

While Medicare beneficiaries in this position have options, they are more limited since the passage of the 21st Century Cures Act, and patients are advised to discuss their options with their physician and current provider of therapy well before transitioning to Medicare to develop a plan for continuation of care.

Drug coverage for other diagnoses. IG therapy for many other diagnoses is usually covered under Medicare Part B in the hospital outpatient setting or in a physician office. For those currently receiving IVIG in these sites of care, the same rules apply for transitioning to Medicare as they do for patients diagnosed with an immune deficiency.

For those receiving IVIG at home, the rules become more complicated. If patients keep their employer's insurance, it's possible no changes will be necessary. Medicare will be billed as the primary insurance; however, reimbursement will be denied as a noncovered benefit with a specific denial code, and then the secondary insurance will be billed. All deductibles and co-payments apply as they did when the employer's insurance was in the primary payment position. This includes government insurance such as Tricare and Champus. However, one item that may not be covered is nursing services. To bill the secondary insurance, the provider must receive the correct denial code from Medicare. Since there is limited coverage for nursing services under Medicare Part A for homebound patients, home infusion providers are not able to bill nursing services and receive a denial to bill the secondary. Therefore, prior to making the change, patients should discuss how nursing services will continue to be covered with the current provider.

If patients who receive IVIG at home do not keep their employer's insurance, one option that will allow them to continue IG therapy is to purchase Medicare Part D insurance, a government program for prescription drugs administered by commercial entities. Medicare Part D consists of many plans, so it can be complicated to choose one. All medications that are prescribed, including IG, should be considered when selecting a plan.

Patients can choose a standard benefit program that may have a lower premium but may not offer assistance through the different phases of coverage. Or, they can choose a plan that may have a slightly higher monthly premium but may have better assistance through coverage phases. The four coverage phases for a standard plan in 2018 are:

1) Deductible: This is paid 100 percent by patients up to a total of $405.

2) Initial coverage limit: For the standard benefit, patients pay 25 percent, and the plan pays 75 percent up to a total out-of-pocket cost of $3,750.

3) Coverage gap: In this phase, also known as the doughnut hole, patients are responsible for most of the charges; however, the drug manufacturer may provide payment assistance in the form of discounts. For brand-name drugs, the discount is 50 percent, and for generics, the discount is 56 percent. The out-of-pocket threshold (TrOOP) is $5,000 in 2018. TrOOP is defined by Medicare as "true out-of-pocket. TrOOP costs are the expenses that count toward a person's Medicare drug plan out-of-pocket threshold. TrOOP costs determine when a person's catastrophic coverage portion of their Medicare Part D prescription drug plan will begin."

4) Catastrophic phase: Once patients (with the assistance of drug manufacturer discounts) have spent a total of $5,000, they become responsible for a smaller portion of the ongoing cost of the drugs, usually 5 percent of the total cost.

Again, there are options. Patients may qualify for Extra Help, a Medicare program to help people with limited income and resources to pay Medicare prescription drug plan costs. When applying for Medicare, it is important for patients to find out if they might qualify for this program. If they don't qualify when first obtaining Medicare, patients should periodically recheck as their finances change to see if they qualify. In addition, some homecare

providers may offer financial assistance programs. If patients are eligible, their financial responsibility can be reduced or waived. And, last, patient advocacy groups also may offer some assistance.

Guidance on selecting the right Medicare Part D coverage can be found at www.medicare.gov, or Medicare assistance can be obtained by calling (800) MEDICARE (633-2273).

The last option for patients who receive IVIG at home is to transition to a hospital outpatient setting where IVIG will be covered at 80 percent under Medicare Part B with the supplemental insurance plan covering the remaining 20 percent. Coverage criteria in the hospital outpatient and physician office setting are based on National or Local Coverage Determinations (NCD or LCD) published by Medicare. The NCD/LCD defines which diagnoses are approved for treatment with IG.

If patients choose to enroll in a Medicare HMO (Medicare Part C or Medicare Advantage Plan), they will automatically be enrolled in a Medicare Part D prescription plan in most cases, and the same rules apply as previously stated. It's important for patients to understand this before choosing a Medicare HMO so they can make the best choice and have the least interruption in therapy.

If patients also have Medicaid, known as being dual eligible, they typically have the most options. Medicare is the primary insurance, Medicaid is the secondary insurance, and they will automatically be enrolled in Medicare Part D. Co-pays for dual-eligible patients are very low, usually in the $3 to $4 range. And, coverage may be 100 percent for infusions in the hospital or at home. However, if patients are infused in a physician office, they should check on their options.

Nursing and supply coverage for all diagnoses. In the physician office and hospital outpatient setting, nursing and supplies are covered under Medicare Part B. In the home, nursing for both IVIG and SCIG is covered under Medicare Part A if patients meet homebound criteria. If patients do not meet homebound criteria, nursing is not covered for the vast majority. Nursing may be covered at home under a Medicare Advantage Plan. Also in the home, supplies for IVIG are not covered, whereas they are covered for SCIG.

For the last several years, HR 1845, the Medicare IVIG Access Act has been in place. The Act provides for a demonstration project, known as the Medicare IVIG Demonstration Project, to examine the benefits of providing coverage and payment for items and services necessary to administer IVIG in the home for patients with primary immunodeficiency disease (PI). The three-year project was scheduled to enroll up to 4,000 Medicare beneficiaries for whom it will allow some payment for nursing services and supplies. The project only applies to situations in which the beneficiary requires IVIG for the treatment of one of the 14 qualifying PI diagnosis codes. Patients receiving SCIG are not eligible for the project unless they wish to switch to IVIG. The demonstration project ended on September 30 of this year, and it is unknown at this time whether the project will affect coverage in the future.

One positive outcome of the 21st Century Cures Act for IG patients is the addition of payment for nursing and supplies effective in 2021. The amount of the payment has not yet been defined, but it can't exceed the payment provided to physician office or hospital outpatient settings for similar services. Many patient organizations, providers and manufacturers are seeking a modification to the effective date to ensure access to care for patients receiving IG in the home setting.

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Know the Options!

Understanding coverage and the options involved with different sites of care and routes of administration is crucial as patients transition to Medicare. Especially when Medicare becomes their primary insurance, patients should be prepared to make changes in their care to optimize coverage. It truly seems that Medicare coverage can be more complex than IG therapy! But by discussing the coverage and options with someone knowledgeable about Medicare guidelines and IG therapy, patients can make the best choices for uninterrupted care when they consider these details well in advance of becoming eligible for Medicare.

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