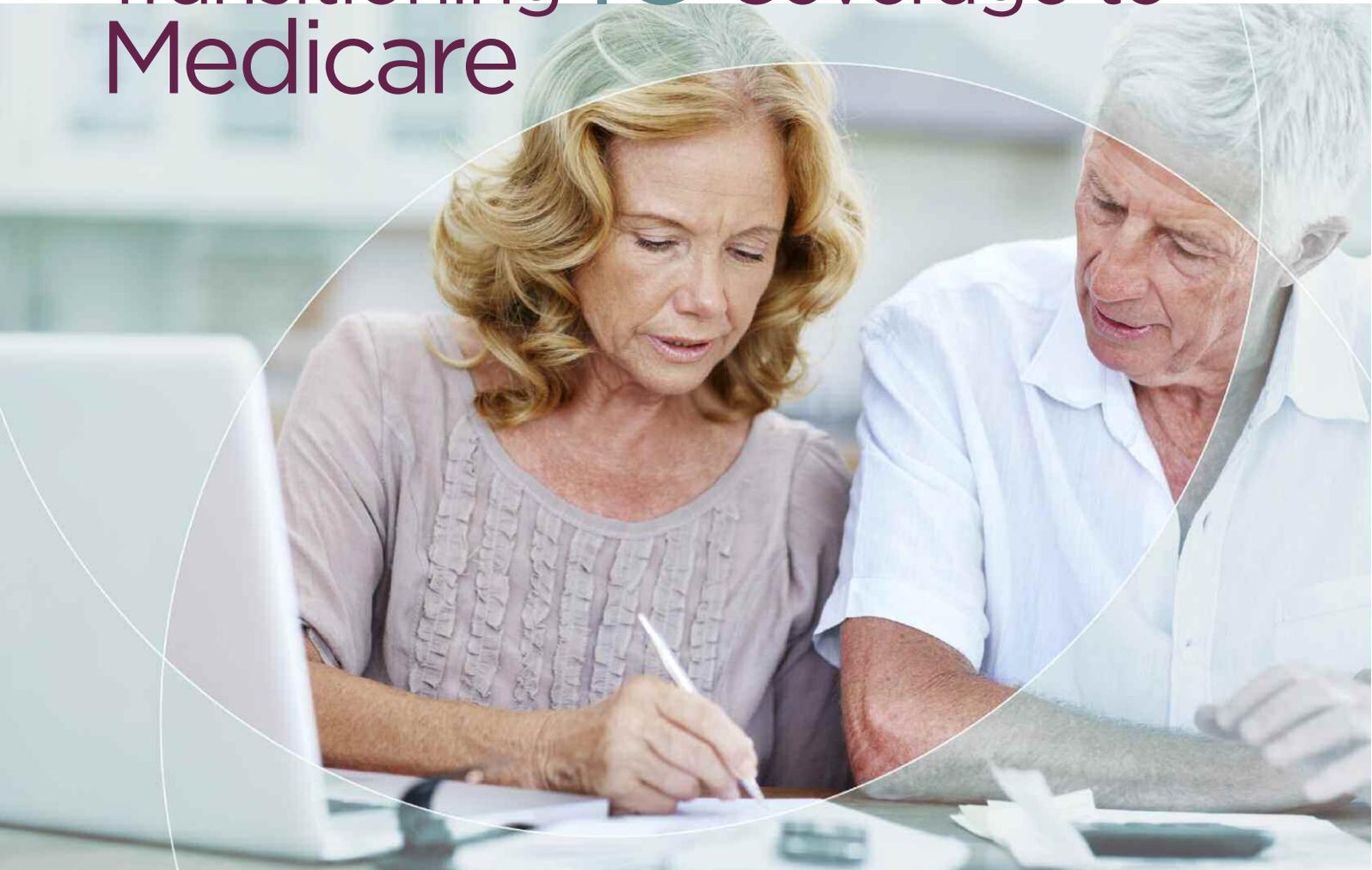


Transitioning IG Coverage to Medicare



Options in Medicare coverage can be more complicated than IG therapy, but these guidelines for individuals turning 65 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, which may require changes in site of care and route of administration 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 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 the 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 detailed information on this, 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 detailed 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 the patients' diagnosis, where they currently receive therapy and whether or not 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's office or home. There is broader coverage in the hospital and physician's office than there is in the home. In the homecare setting, coverage is limited to five specific diagnosis codes:

- 279.04: congenital hypogammaglobulinemia (aka Bruton's agammaglobulinemia)
- 279.05: immune deficiency with increased IgM
- 279.06: common variable immune deficiency
- 279.12: Wiskott-Aldrich syndrome
- 279.2: severe combined immune deficiency

COMPARED WITH ALL OTHER INSURANCE PLANS, MEDICARE PROBABLY VARIES MOST IN ITS COVERAGE POLICIES FOR IG THERAPY.

Unfortunately, IVIG is not reimbursed very well under Medicare Part B. For some providers, Medicare reimbursement is below their cost to purchase IVIG, and this may cause them to ask patients to change their site of care or route of administration. This is mostly true for patients who receive IVIG in the physician's office and at home.

Patients who receive IVIG in a physician's 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. There are five SCIG products: Gammagard Liquid (Baxalta), Gamunex-C (Grifols), Gammaked (Kedrion Biopharma), Hizentra (CSL Behring) and HYQVIA (Baxalta). HYQVIA is the most recent addition to SCIG products, and it 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, more recently, that decision has been partially reversed. The manufacturer of HQVIA, Baxalta, 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.

Many Medicare beneficiaries in this position have successfully changed to SCIG and have learned to self-administer in their home setting. SCIG offers many benefits, including a lower incidence of side effects, no need to start IV lines, and the ability to choose when and where to administer therapy. Most home infusion providers will teach patients how to self-administer SCIG. And, there are many patient education materials, including DVDs, that demonstrate SCIG self-administration. Those interested in learning more should ask their physician to obtain the materials for them, or they can go to the website of the manufacturers of SCIG products: www.gammagard.com, www.gamunex-c.com, www.gammaked.com, www.hizentra.com, www.hyqvia.com.

Patients receiving IVIG at home may be asked to switch to SCIG. If this is not an option for patients, they may be asked to transfer their services to a hospital outpatient infusion center. Patients' homecare providers should be discussing this and reviewing these options with them well before transitioning to Medicare so there is time to facilitate a smooth transfer. If a provider hasn't started discussing this with them prior to transitioning to Medicare, patients should contact their homecare provider to discuss services and options.

Patients who self-administer SCIG will not likely be asked to make a change because SCIG is not reimbursed at the low IVIG rate. Patients who receive IVIG in the hospital also will not likely be asked to make a change. However, they should speak with someone in their infusion center who can explain Medicare coverage to them and confirm there will be no change.

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's 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.

If receiving IVIG at home, the rules become more complicated. If patients will keep their employer's insurance, it's possible that no changes will be necessary. Medicare will be billed; however, reimbursement will be denied, 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.

If patients who receive IVIG at home will not keep their employer's insurance, one option that will allow them to continue IG therapy is to purchase Medicare Part D insurance, which is 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 the coverage phases. The four coverage phases for a standard plan in 2015 are:

1. **Deductible:** This is paid 100 percent by the member up to a total of \$320.
2. **Co-insurance/co-payment:** For the standard benefit, the patient pays 25 percent and the plan pays 75 percent up to a total out-of-pocket cost of \$2,960. This means the patient pays a total of \$651.25 in this phase.
3. **Coverage gap:** In this phase, also known as the doughnut hole, the patient is responsible for most of the charges; however, the drug manufacturer may provide payment assistance. For brand-name drugs, the patient's responsibility is 45 percent, and for generics, the patient's responsibility is 65 percent. In 2015, the total doughnut hole amount is \$3,713.75, of which the patient may be responsible for all or as little as \$1,738.
4. **Catastrophic phase:** Once a patient (with the assistance of the drug manufacturer) has spent a total of \$4,700, the patient becomes 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 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 the 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 100 percent under Medicare Part B and a supplemental insurance plan.

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, also 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's office, they should check on their options.

Nursing and supply coverage for all diagnoses. In the physician's 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 the patient meets homebound criteria. If the patient does not meet homebound criteria, nursing is not covered for the vast majority of patients. 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.

However, on January 10, 2013, President Obama signed into law HR 1845, the Medicare IVIG Access Act. 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 immune deficiency disease. The three-year project will 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 five qualifying immune deficiency diagnosis codes. Patients receiving SCIG are not eligible for the project unless they wish to switch to IVIG.

Medicare beneficiaries can apply for the project by visiting the NHIC Corp. website at www.medicarenhic.com. However, there is one cautionary note: Approval for the project does not guarantee coverage. The application and approval process do not specifically list the five covered home diagnosis codes; rather, there is a blanket statement of: "I attest that I am treating this patient, that the patient has primary immune deficiency disease, and is a candidate for home IVIG." This has led to approval for some patients under the project, but they don't have a diagnosis that qualifies for drug coverage at home.

PATIENTS MAY QUALIFY FOR EXTRA HELP, A MEDICARE PROGRAM TO HELP PEOPLE WITH LIMITED INCOME AND RESOURCES PAY MEDICARE PRESCRIPTION DRUG PLAN COSTS.

Know the Options!

Understanding coverage and the options for site of care and route of administration is crucial as patients transition to Medicare. When Medicare becomes the primary insurance, patients need to know whether they will be asked to make changes in their care. Medicare coverage can be more complex than IG therapy! But by discussing the coverages and options with someone knowledgeable in Medicare guidelines and IG therapy coverage, patients can make the best choices for uninterrupted care. ■

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Editor's note: This is an update of the original article that appeared in the February-March 2013 issue of IG Living.