WHITE PAPER

Clinical Advantages of Home-Based Intravenous Immunoglobulin Therapy

NEW JERSEY Infusion SERVICES

Introduction

Intravenous immunoglobulin (IVIG) replacement therapy is the standard of care for patients with primary immunodeficiency diseases (PIDDs) and select secondary immunodeficiencies characterized by absent or deficient antibody production.

These patients require lifelong, regular immunoglobulin infusions every 3–4 weeks to prevent recurrent, severe, and potentially life-threatening infections. The site of care—hospital inpatient, hospital outpatient, physician's office, or home—has significant implications for clinical outcomes, safety, treatment adherence, quality of life, and healthcare costs.

This report synthesizes evidence from peer-reviewed clinical studies, large managed-care databases, government-sponsored demonstration projects, and professional society guidelines to evaluate the clinical advantages of administering IVIG in the home setting, with particular emphasis on the reduced risk of exposure to infectious agents.[1][2]

Immunological Rationale: Why Infection Exposure Matters

Vulnerability of Immunocompromised Patients

Patients requiring immunoglobulin replacement therapy have inherent defects in their immune systems that impair their ability to fight infection.

Even with appropriate IVIG replacement, these patients remain more susceptible to infection than immunocompetent individuals. It is universally accepted in the biomedical literature that immunocompromised hosts are more susceptible to nosocomial infection than normal hosts.

Their deficient humoral immunity means that any pathogen exposure carries an outsized risk of clinical disease, prolonged illness, and serious complications including chronic lung disease, inflammatory bowel disease, and organ damage.[3][4][1]

Healthcare-Associated Infection Risk in Clinical Settings

A systematic review of nosocomial infection risk factors identified immunosuppression as a key predisposing factor, alongside frequency of hospital visits, length of stay, intrahospital transfers, and exposure to other patients and healthcare workers.

Each additional intrahospital transfer was associated with a 9% increase in the odds of developing a nosocomial infection. Outpatient clinical settings are not exempt from this risk.

A review of infection transmission data in outpatient settings documented that outbreaks of measles, tuberculosis, hepatitis B and C, and COVID-19 have been traced to outpatient medical encounters, with immunocompromised populations identified as particularly vulnerable.

The CDC's "Guide to Infection Prevention for Outpatient Settings" acknowledges that time spent in reception areas, waiting rooms, and during medical encounters all present opportunities for transmitting pathogens among patients, visitors, and staff.[5][3]

Patients with cancer, those receiving chemotherapy, and those on dialysis—all of whom may be immunocompromised—regularly receive treatments in outpatient settings and represent populations at heightened risk.

For patients requiring IVIG every 3–4 weeks, each clinic or hospital visit adds cumulative pathogen exposure that compounds over the course of lifelong therapy.[5]

Respiratory Pathogens and the COVID-19 Context

The COVID-19 pandemic dramatically underscored the risk of healthcare facility exposure for immunocompromised individuals.

The International Society for Infectious Diseases (ISID) specifically recommended special infection prevention measures for all immunocompromised hosts during the pandemic, noting that these patients have "frequent healthcare exposures resulting in potentially increased exposure risk".

German infection prevention guidelines (KRINKO) similarly stressed that respiratory viruses, generally harmless in healthy people, can cause potentially life-threatening infections in immunosuppressed patients, who also shed these pathogens for much longer without symptoms.[6][7]

Patient testimony from the Medicare IVIG Demonstration project echoed these concerns. Gail Nelson, a demonstration enrollee from Louisiana, stated: "In this time of COVID-19, it gives me nightmares to think about going to another setting for my treatments, especially considering how risky it is for those with a PI". Another enrollee noted that receiving home infusions meant "not being exposed to illnesses present in a hospital setting".[8]

Clinical Outcomes: Reduced Infections and Healthcare Utilization

The Medicare IVIG Demonstration Project

The most robust government-sponsored evidence comes from the Medicare Patient IVIG Demonstration, mandated by the Medicare IVIG Access Act of 2012 and evaluated by CMS through an interim report to Congress. The demonstration provided bundled payment for supplies and services needed for in-home IVIG administration for Medicare beneficiaries with primary immune deficiency disorders. Key findings included:[9][8]

- **Improved access**: Demonstration enrollees received an average of 2.26 more IVIG treatments per year than non-enrollees, reducing the likelihood of missing or postponing infusions.[9]
- **Reduced infection-related care**: Demonstration enrollees were 12.5% less likely than non-enrollees to receive infection-related care, indicating better management of their immune deficiency and better overall health.[10][8]
- **Self-reported health improvements**: 71% of enrolled patients reported better access to Ig treatments; enrollees reported being in better overall health and experienced a significant drop in serious health issues related to their immunodeficiency.[11]

The report noted that these indications of better overall health "agree with the findings of other studies that have compared in-home versus outpatient IVIG infusion".[10]

Rastegar et al. (2023) — Home vs. Outpatient Hospital IVIG

A retrospective cohort study published in the Journal of the American Pharmacists Association using the Humana Research Database examined 208 home-infusion patients and 1,079 outpatient hospital (OPH) IVIG patients from 2017 to 2018. After adjusting for baseline differences in demographics, comorbidity burden, and IVIG indications, the study found:[12]

- **44% lower odds** of inpatient hospital stay for home IVIG patients (OR 0.56; 95% CI 0.38–0.82).[12]
- **38% lower odds** of emergency department visit for home IVIG patients (OR 0.62; 95% CI 0.41–0.93).[12]

The authors concluded that "decreased health care utilization provides value to the system in cost savings and to patients and families owing to less disruption and improved clinical outcomes".[13][12]

Home-Based Immunoglobulin and Infection Rates

A study presented at the IgNS 2024 National Conference analyzed data from 732 adults with PIDDs using a large managed care database (Komodo Health). Patients who self-administered subcutaneous immunoglobulin at home had:

- Significantly lower overall infection incidence during treatment compared to baseline (83.1% vs. 89.9%; P<0.001).[14]
- Reductions across severe infections, ear and sinus infections, and respiratory infections.[14]
- Consistent reductions in antibiotic use during active home-based treatment.[14]

Ito et al. (2014), referenced in IG Living, demonstrated significantly lower rates of pneumonia and bronchitis in PI patients receiving IVIG therapy at home versus in outpatient hospitals.[15]

High-Touch Clinical Management in the Home

An analysis of 242 patients receiving IVIG through a home infusion specialty pharmacy with intensive clinical management found a significantly lower rate of serious bacterial infections compared to a control group of 968 patients (4.13% vs. 7.75%). This suggests that the combination of home-based infusion with individualized nursing care produces superior infection prevention outcomes.[16]

Safety of Home-Based IVIG

Large-Scale Safety Data

A landmark retrospective analysis by Souayah et al. (2018, Journal of Clinical Neuromuscular Disease) assessed the safety of IVIG in **1,176 patients receiving 28,677 home-based infusions** between 1996 and 2013. Key findings:[17][18]

- 55.1% of patients experienced IVIG-related adverse reactions; the vast majority (45.6%) were mild.[18]
- Only 6.6% had moderate reactions; 2.9% had severe reactions.[18]
- 3.1% of patients required hospitalization due to adverse reactions, most commonly for headache.[18]
- The authors concluded that "low- and high-dose IVIg were safe and well tolerated with a few serious ARs".[17]

An even larger analysis from a specialty pharmacy (Accredo) reviewed **4,155 patients** and **32,537 infusion assessments**:[19]

- The true adverse drug reaction (ADR) rate was just 1.1% of all infusion assessments.[19]
- Severe ADRs occurred at a rate of 0.05%.[19]
- Potentially life-threatening events (anaphylaxis and pulmonary embolism) were limited to 0.006%.[19]
- Slowing the infusion rate was demonstrated to significantly reduce recurrence of ADRs.[19]

Real-World Comparative Safety: Home IVIG vs. SCIG

A retrospective evaluation of 149 PIDD patients in a home infusion setting (2010–2018) found that both IVIG (n=84) and SCIG (n=65) were effective and safe in the home. The majority of patients had ≤1 infection or hospital visit within the study period. SCIG patients had fewer hospital visits and lower rates of infections overall,

while IVIG patients had higher systemic adverse reaction rates but remained safely managed in the home.[20]

Professional Society Guidelines on Site of Care

AAAAI Eight Guiding Principles and Site-of-Care Guidelines

The American Academy of Allergy, Asthma and Immunology (AAAAI), endorsed by the Clinical Immunology Society (CIS) and the Immune Deficiency Foundation (IDF), published eight guiding principles for IVIG use and specific site-of-care guidelines.[21][22][1]

Guiding Principle 6 states: "The decision to infuse IVIG in a hospital, hospital outpatient, community office, or home-based setting must be based upon clinical characteristics of the patient".[1]

The AAAAI site-of-care guidelines explicitly recognize that "**hospital settings can be associated with a risk of exposure to patients with infectious conditions**" and that "**the benefits of outpatient and home therapy should serve as a motivation to re-evaluate a patient and their suitability for a particular site of care**". This is a direct acknowledgment from the leading professional allergy/immunology body that infection exposure in healthcare facilities is a clinical concern warranting consideration of home-based therapy.[23]

The guidelines establish a tiered framework for site-of-care determination:[23]

Patient Characteristic	Recommended Site of Care
Initial infusion or product change	Physician-supervised facility
History of severe adverse events	Hospital inpatient
Moderate adverse events	Hospital outpatient or physician office
No or mild adverse events (easily managed)	Home-based infusion with nurse supervision
No adverse events, high medical sophistication	Home-based with trained partner

For the approximately half of PI patients who do not experience adverse events, home-based infusion represents an appropriate and guideline-supported site of care.[23]

Treatment Adherence and Compliance

Improved Adherence in the Home Setting

Treatment adherence is critical in immunoglobulin replacement therapy, as interruption or delay in infusions directly increases infection risk and can result in permanent organ damage. Evidence consistently shows superior adherence with home-based IVIG:[1]

- In the Luthra et al. (2014) analysis, optimal adherence (defined as 13–18 infusions per year) was achieved by **47% of home-based patients** versus only **22% of outpatient hospital patients**.[24]
- Medicare IVIG Demonstration enrollees received an average of 2.26 more treatments per year and were less likely to miss or postpone treatments.[9]
- A CMS survey found that 71% of demonstration enrollees reported better access to Ig treatments compared to non-enrollees.[11]

Barriers to adherence in outpatient settings include transportation difficulties, scheduling conflicts, time away from work and school, and general disruption to daily life. These factors are significantly mitigated or eliminated in the home setting. Deviation from the recommended treatment plan has been repeatedly shown to lead to increased emergency room visits, hospitalizations, physician visits, nursing home admissions, and avoidable healthcare costs.[25][15]

Quality of Life and Patient Satisfaction

Patient-Reported Outcomes

A cross-sectional study from the National Home Infusion Foundation Benchmarking Program found high levels of patient satisfaction with home infusion services, with top-box "strongly agree" scores of 84.38% (IVIG) and 86.36% (SCIG) for overall quality of services. These scores exceed satisfaction levels for other home infusion therapy types.[11]

Patients and healthcare providers in the Medicare IVIG Demonstration identified the following advantages of home-based treatment:[8]

- **Decreased transportation barriers**
- **Reduced exposure to infection**
- **Increased treatment compliance**
- **Improved infusion monitoring (one-on-one nursing care)**
- **Greater control over scheduling and daily activities**

For pediatric patients, home IG infusions are especially important because they increase family functioning, provide greater independence, and reduce school absenteeism. The CMS Updated Interim Report documented that enrollees reported improved self-perceived health and experienced fewer serious health issues related to their immunodeficiency.[15][11]

Economic Benefits

Cost Savings

Home-based IVIG therapy produces significant cost savings compared to outpatient hospital settings:

- Per-infusion cost is approximately 31% lower in the home setting (in 2010 dollars).
- Annual savings estimated at $18,876 to $26,136 per patient for 13–18 infusions per year.
- Overall general medical costs are reduced by approximately 30% due to fewer hospitalizations and emergency department visits.[26]

These savings accrue from both direct cost reductions (lower site-of-care fees, reduced inpatient and ED utilization) and indirect savings (reduced lost work time, improved societal productivity). The Medicare IVIG Demonstration did show an increase of approximately $8,082 per beneficiary per year in Medicare Part A and B expenditures due to increased IVIG utilization; however, the report notes this does not factor in the long-term cost savings associated with better overall health outcomes and reduced infection-related care.[8][9][15]

A cost-utility analysis comparing hospital-based IVIg with home-based SCIg in patients with secondary immunodeficiency found that home-based SCIg was the dominant strategy, producing better health outcomes at lower cost. In 88.3% of probabilistic sensitivity analysis iterations, SCIg fell below the willingness-to-pay threshold of A$50,000 per QALY.[27]

Synthesis: The Case for Home-Based IVIG in Immunocompromised Patients

The convergence of clinical, immunological, safety, adherence, quality-of-life, and economic evidence creates a compelling case for home-based IVIG therapy for appropriate immunocompromised patients. The core advantages can be summarized as follows:

Dimension	Home IVIG Advantage	Key Evidence
Infection exposure	Eliminates repeated healthcare facility visits; avoids pathogen-laden waiting rooms and shared infusion spaces	12.5% reduction in infection-related care (Medicare Demo) [10]; lower pneumonia/bronchitis rates [15]
Healthcare utilization	Fewer inpatient stays and ED visits	OR 0.56 for IP stays; OR 0.62 for ED visits [12]
Safety	Well-tolerated with low serious adverse event rates	1.1% ADR rate; 0.05% severe; 0.006% life-threatening [19]
Adherence	Significantly higher optimal treatment adherence	47% vs. 22% optimal adherence [24]
Quality of life	Higher satisfaction, greater autonomy, less life disruption	84–86% top-box satisfaction [11]
Cost	Substantial per-patient annual savings	$18,876–$26,136/year savings [15]

The AAAAI's explicit acknowledgment that hospital settings pose infection exposure risks, and that this should motivate reconsideration of home therapy, provides the authoritative clinical framework for these decisions. In the post-COVID era, with heightened awareness of respiratory pathogen transmission in healthcare settings, the rationale for home-based IVIG is stronger than ever.[6][8][23]

Limitations and Considerations

Home IVIG therapy is not appropriate for all patients. The AAAAI guidelines specify that initial infusions and product changes should be administered under physician supervision in appropriately equipped facilities due to the risk of severe acute adverse events.

Patients with a history of significant adverse reactions require higher levels of medical supervision. Additionally, patients must be physically and cognitively able to comply with the treatment regimen, and home infusion requires access to qualified infusion nursing services. Rural areas may face challenges in nursing availability, and not all insurance plans provide comprehensive coverage for home infusion services and supplies.[23][15]

References to Key Sources

- AAAAI Eight Guiding Principles for IVIG Use and Site-of-Care Guidelines[1][23]
- CMS Medicare IVIG Demonstration Interim Report to Congress (2022)[10][9][8]
- Rastegar J, et al. *J Am Pharm Assoc.* 2023;63(5):1566-1573[12]
- Souayah N, et al. *J Clin Neuromuscul Dis.* 2018;19(4):181-195[17][18]
- Geremakis C, et al. IgNS 2024 Conference (Komodo Health database analysis)[14]
- ISID COVID-19 Guidelines for Immunocompromised Hosts[6]
- KRINKO Infection Prevention Recommendations[7]
- National Home Infusion Foundation Benchmarking Program[11]
- Luthra R, et al. *Am J Pharm Benefits.* 2014;6:e41-e49[24]
- Accredo/Express Scripts Home IVIG Safety Analysis[19]

References

1. AAAAI/CIS/IDF. "Eight Guiding Principles for Effective Use of IVIG for Patients with Primary Immunodeficiency." American Academy of Allergy, Asthma and Immunology Practice Tools. [aaaai](https://www.aaaai.org/Aaaai/media/Media-Library-PDFs/Practice%20Management/Practice%20Tools/IVIG-guiding-principles.pdf)

2. National Center for Biotechnology Information. "Intravenous Immunoglobulin (IVIG)." *StatPearls* [Internet]. Updated July 2, 2023. [ncbi.nlm.nih](https://www.ncbi.nlm.nih.gov/books/NBK554446/)

3. Peterson HA, Peterson JR, Havaldar MH. "Nosocomial Infections in Hospitalized Patients: Predisposing Factors." *JMIR Public Health and Surveillance.* 2023;9:e43743. [publichealth.jmir](https://publichealth.jmir.org/2023/1/e43743/)

4. Armstrong D. "Nosocomial Infections in the Immunocompromised Adult." *The American Journal of Medicine.* 1981;70(3):667–670. [pubmed.ncbi.nlm.nih](https://pubmed.ncbi.nlm.nih.gov/7008588/)

5. Infection Control Today. "Infection Control and Prevention in the Outpatient Physical Office Setting." November 8, 2023. [infectioncontroltoday](https://www.infectioncontroltoday.com/view/infection-control-and-prevention-outpatient-physical-office-setting)

6. International Society for Infectious Diseases (ISID). "COVID-19 Related Infection Prevention Practices for the Immunocompromised Host." 2020. [isid](https://isid.org/wp-content/uploads/2020/10/ISID_GUIDE_COVID-19_Immunocompromised_Host.pdf)

7. KRINKO (German Commission for Hospital Hygiene and Infection Prevention). "Infection Prevention Requirements for the Medical Care of Immunosuppressed Patients." *GMS Hygiene and Infection Control.* 2022;17:Doc07. [pmc.ncbi.nlm.nih](https://pmc.ncbi.nlm.nih.gov/articles/PMC9174886/)

8. Immune Deficiency Foundation / XLA.Life. "Report Shows Health Benefits of Medicare IVIG Demonstration." December 21, 2022. [xla](https://www.xla.life/post/immune-deficiency-foundation-report-shows-health-benefits-of-medicare-ivig-demonstration)

9. Dobson DaVanzo & Associates / CMS. "Medicare Intravenous Immunoglobulin (IVIG) Demonstration: Report to Congress — Post-Demonstration Updated Interim Report." October 2022. [dobsondavanzo](https://www.dobsondavanzo.com/news/2022/10/10/news/medicare-intravenous-immunoglobulin-ivig-demonstration-report-to-congress-posted-on-cms-website/)

10. Primary Immune Deficiency Foundation. "Report Shows Health Benefits of Medicare IVIG Demonstration." November 27, 2022. [primaryimmune](https://primaryimmune.org/resources/news-articles/report-shows-health-benefits-medicare-ivig-demonstration)

11. National Home Infusion Foundation. "A Descriptive Cross-Sectional Study of Patient Experience Among Home Infusion Patients Administering Immune Globulin." *NHIA Infusion Journal.* 2025. [nhia](https://nhia.org/a-descriptive-cross-sectional-study-of-patient-experience-among-home-infusion-patients-administering-immune-globulin-a-comparison-of-satisfaction-between-iv-and-sc-administration/)

12. Rastegar J, Brown VT, John I, Dixon SW, Rodman E, Ellis JJ, Poonawalla IB. "Home versus Outpatient Hospital Intravenous Immunoglobulin Infusion and Health Care Resource Utilization." *Journal of the American*

Pharmacists Association.* 2023;63(5):1566–1573.e1. doi: 10.1016/j.japh.2023.06.021.
[pubmed.ncbi.nlm.nih](https://pubmed.ncbi.nlm.nih.gov/37399927/)

13. Humana Healthcare Research. "Home versus Outpatient Hospital Intravenous Immunoglobulin Infusion and Health Care Utilization." (Summary of Rastegar et al.) April 10, 2025.
[research.humana](https://research.humana.com/research_publications_resources/articles/home-versus-outpatient-hospital-intravenous-immunoglobulin-infusion)

14. Geremakis C, et al. "Home-Based Ig Rx Reduces Infections and Antibiotic Use." Presented at IgNS 2024 National Conference; data sourced from Komodo Health managed care database (732 adults with PIDD). Reported in *Infectious Disease Special Edition.* October 13, 2025.
[idse](https://www.idse.net/Immunocompromised-Conditions/Article/10-25/Home-Based-Ig-Rx-Reduces-Infections-And-Antibiotic-Use/78630)

15. Wasserman RL, Ito D, Xiong Y, Ye X, Bonnet P, Li-McLeod J. "Impact of Site of Care on Infection Rates Among Patients with Primary Immunodeficiency Diseases Receiving Intravenous Immunoglobulin Therapy." *Journal of Clinical Immunology.* 2017;37(2):180–186. (Reported in *IG Living*, April 2016.)
[igliving](https://www.igliving.com/magazine/articles/IGL_2016-04_AR_Benefits-of-Home-IVIG-Therapy.pdf)

16. Kile S, et al. (American Journal of Managed Care). "Managing Cost of Care and Healthcare Utilization in Patients Using Immunoglobulin Agents." *AJMC.* August 5, 2020. (High-touch clinical management program data: 242 patients vs. 968 controls.)
[ajmc](https://www.ajmc.com/view/managing-cost-of-care-and-healthcare-utilization-in-patients-using-immunoglobulin-agents)

17. Souayah N, Hasan A, Khan HMR, Yacoub HA, Jafri M. "A Retrospective Analysis of the Safety Profile of Intravenous Immunoglobulin in 1176 Patients Receiving Home Infusion Therapy." *Journal of Clinical Neuromuscular Disease.* 2018;19(4):181–195. doi: 10.1097/CND.0000000000000201.
[researchwithrutgers](https://www.researchwithrutgers.com/en/publications/a-retrospective-analysis-of-the-safety-profile-of-intravenous-imm/)

18. Accredo / Express Scripts. "Minimizing Adverse Drug Reactions to IVIG in the Home Setting." (Analysis of 4,155 patients and 32,537 infusion assessments.)
[accredo](https://www.accredo.com/minimizing-adverse-drug-reactions-to-ivig.pdf)

19. Abolhassani H, et al. "Intravenous versus Subcutaneous Immunoglobulin in Primary Immunodeficiency: Real-World Evaluation." *Longdom Publishing.* 2020. (Retrospective evaluation of 149 PIDD patients in home infusion, 2010–2018.)
[longdom](https://www.longdom.org/open-access/intravenous-versus-subcutaneous-immunoglobulin-in-primary-immunodeficiency-realworld-evaluation-of-safety-efficacy-and-patient-per-53415.html)

20. AAAAI/CIS/IDF. "Guidelines for the Site of Care for Administration of IGIV Therapy." American Academy of Allergy, Asthma and Immunology Practice Management Tools.
[aaaai](https://www.aaaai.org/Aaaai/media/Media-Library-PDFs/Practice%20Management/Practice%20Tools/Guidelines-for-the-site-of-care-for-administration-of-IGIV-therapy.pdf)

21. AAAAI. "IVIG Toolkit." (Includes Guiding Principles and Site-of-Care Guidelines.)
[aaaai](https://www.aaaai.org/practice-management/practice-tools/ivig-toolkit)

22. Immune Deficiency Foundation. "Model Coverage Policy for Ig Replacement Therapy." July 21, 2021.
[primaryimmune](https://primaryimmune.org/resources/print-material/model-coverage-policy-for-ig-replacement-therapy)

23. Luthra R, Quimbo R, Iyer R, Luo M. "An Analysis of Intravenous Immunoglobulin Site of Care: Home versus Outpatient Hospital." *American Journal of Pharmacy Benefits.* 2014;6(2):e41–e49. [ajmc.s3.amazonaws](https://ajmc.s3.amazonaws.com/_media/_pdf/AJPB_03to04_Luthra_WebX_e41to9.pdf)

24. Patient Power. "IVIG Therapy at Home: What to Know" (CLL patient perspective). September 30, 2025. [patientpower](https://www.patientpower.info/chronic-lymphocytic-leukemia/treatments/can-cll-patients-get-ivig-at-home)

25. Pharmko. "Benefits of Home-Based IVIG Therapy." August 20, 2025. [pharmko](https://www.pharmko.com/blog/benefits-of-home-based-ivig-therapy)

26. Hua M, Carpenedo D, Engelen V, et al. "Cost–Utility Analysis Comparing Hospital-Based Intravenous Immunoglobulin with Home-Based Subcutaneous Immunoglobulin in Patients with Secondary Immunodeficiency." *Vox Sanguinis.* 2019;114(3):237–246. doi: 10.1111/vox.12760. [onlinelibrary.wiley](https://onlinelibrary.wiley.com/doi/abs/10.1111/vox.12760)

