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**Case Study: Successful transition to ASCENIV therapy with improved PROMs**

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**Objective:** The purpose of this case study was to demonstrate the use of patient reported outcome measures (PROMs) to evaluate the effectiveness of therapy success and outcomes in a patient with primary immunodeficiency.

**Background:** A 74-year-old Caucasian woman receives IVIg for the treatment of selective deficiency of immunoglobulin G [IgG] subclasses, ICD-10 D80.3. Past medical history includes chronic obstructive lung disease and hypothyroidism. After 4 months of receiving IVIg therapy in the home, the patient was transitioned to another IVIg product, ASCENIV, for the continued treatment of her condition. A multidisciplinary team conducted a retrospective review of her medical records from the start of care to current status. This included customized clinical assessments specific to primary immunodeficiency, wellness, and fatigue that were performed by the specialty infusion pharmacy and reported through the proprietary clinical outcomes program SoleMetrics<sup>®</sup>. The review also included progress notes, nursing assessments, and physician office visit notes.

**Table 1.**  
Soleo Health Wellness Scale.

|                             | Score   |   |                                      |  |  |
|-----------------------------|---|---|--------------------------------------|--|--|
|                             | 1   | 2   | 3                                    | 4  | 5  |
| Energy Level                | Lots of energy and can do the things I want to do | Can do most things, may need to rest at times | Normal level of energy               | Feel tired most of the time sitting and not engaging in activities | Staying in bed most of the day due to fatigue, tired all day |
| Mood                        | In a great place and feeling positive             | Good mood most of the time                    | Feel even tempered                   | Feel blah some of the time, sometimes feel cranky                  | Depressed all of the time, irritable and annoyed with others |
| Sleep Patterns              | Great restful sleep                               | Good sleep                                    | No real problems                     | Have problems falling asleep or staying asleep                     | Insomnia   |
| Stress Level                | Very relaxed, feel at peace                       | Relaxed                                       | Normal stress level and feeling calm | Somewhat stressed  | Very stressed  |
| Overall Health and Wellness | Feel great  | Feel good                                     | Feel Okay                            | Feel bad   | Feel bad all the time  |

**Methods:** The patient assessment and completion of select PROMs were performed prior to each dispense of the medication or at the time of a home infusion nursing visit. Wellness was assessed using the Soleo Health Wellness scale and an immunology disease-specific assessment. **Summary:** Wellness was based on five questions related to overall wellness, mood, energy, sleep patterns, and stress. Scores were reported on a 1–5 scale, with one being the best. Other factors used were a subjective statement by the patient, “How are you feeling today,” emergency department and hospitalization records, reported infections, and medication changes. While on the previous IVIg regimen, the patient reported an average wellness score of 16.6 compared to an average of 13 while on ASCENIV. Additionally, while on ASCENIV the patient reported no infections, no emergency or hospital visits, and improvement in the ability to exercise and participate in family and social activities. ASCENIV is an Ig product manufactured to have high concentration of neutralizing antibodies to nine common respiratory viral infections, including respiratory syncytial virus. These characteristics may contribute to improved outcomes.

**Conclusions:** After 6 months of ASCENIV therapy, the patient showed significant improvement in her overall wellbeing and response to therapy.

**Keywords:** Primary immunodeficiency, ASCENIV, PROMs, Wellness

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**Table 2.**  
Patient Wellness Scores.

|                   | How would you describe your feeling of health and wellness? | How would you describe your energy level and ability to participate in activities? | How would you describe your mood? | How would you describe your sleep patterns? | How would you describe your stress level? | Total score |
|-------------------|---|--|-----------------------------------|---|---|-------------|
| 02/10/2022        | 3   | 4  | 2                                 | 3   | 4   | 16          |
| 03/09/2022        | 3   | 4  | 2                                 | 3   | 5   | 17          |
| 04/05/2022        | 3   | 4  | 2                                 | 4   | 5   | 18          |
| 04/30/2022        | 3   | 4  | 2                                 | 4   | 4   | 17          |
| 06/02/2022        | 3   | 4  | 2                                 | 2   | 4   | 15          |
| Change to ASCENIV |   |  |                                   |   |   |             |
| 06/30/2022        | 3   | 2  | 2                                 | 3   | 3   | 13          |
| 07/08/2022        | 3   | 2  | 2                                 | 3   | 3   | 13          |
| 08/06/2022        | 3   | 2  | 2                                 | 3   | 3   | 13          |
| 09/24/2022        | 3   | 2  | 2                                 | 3   | 3   | 13          |
| 10/01/2022        | 3   | 2  | 2                                 | 3   | 3   | 13          |
| 11/01/2022        | 3   | 2  | 2                                 | 3   | 3   | 13          |