Managing demand for immunoglobulins: PIDs are a priority indication at all times

The global demand for immunoglobulin (Ig) replacement therapies is growing annually at 6–8% across a broad range of indications. Whilst strategies to manage Igs demand are urgently needed and should be swiftly implemented in all countries, the fact remains that some countries are still struggling to get access to Ig therapies. Ensuring appropriate, equitable and stable access to Igs in all countries require both increased plasma supply with much more regionally balanced plasma collection and improved fractionation technology to optimize yield from each litre of plasma[4].

Igs are plasma derived medicinal products (PDMPs) used in the treatment of several diseases and conditions.

Around 60% of patients with primary immunodeficiencies (PIDs) need Igs throughout their lives to keep the levels of antibodies within a "suitable" threshold to fight infections and prevent mortality.

No alternative treatments are available for patients with PIDs requiring Ig therapies[1]. Antibiotics are no alternative for Ig therapies.

Reports speak about approximately 100 different uses of intravenous Ig (IVIg), although regulatory agencies have only approved a few indications for its usage[2]. It should be noted that there are a number of off-label indications that are not supported by data[3]. Indications for Ig therapy also vary depending on the region/country as does use in a wide range of other off-license indications[4]

Countries should acknowledge that Igs are an "essential medicine for both adults and children" according to the WHO as a treatment for primary immunodeficiencies and should ensure that all patients who need it have access to regular and sufficient quantities of Ig to be clinically effective[5].

Ig therapies should be prioritised and ring-fenced for PIDs since there are clear life-threatening indications, proven efficacy, and no alternative treatments available[6,7].

A process for Ig demand management should be adopted to ensure appropriate access for all patients who need Ig treatment[8] including for those who live in remote areas far from expert centres in main cities.

- Demand management plans need to be implemented to ensure continuity of supply to all patients with PIDs who need Ig, particularly in times of product shortage (whether lack of plasma collection or manufacturing issues, contamination incidents, or other reasons).

National decision-making around the supply of Ig therapies should always include the expertise of clinical experts and patient representatives in a collaborative way.

In times of shortages or supply tensions:

- Stable PID patients should not have their therapy reduced, altered in terms of dose or cycle. Changes, including brand changes, should be driven on clinical grounds only.

- Newly diagnosed PID patients should not be denied access to appropriate treatment.

Plurality of Ig suppliers and a wide range of both intravenous Ig (IVIg) and subcutaneous Ig (SCIg) therapies is the way to ensure stable and sustainable treatment.

Healthcare systems should diversify the supply of SCIg and IVIg. Ensuring a range of Ig therapies is available for optimal individualised care.

This statement was prepared by the IPOPI SAFE Task Force

About the SAFE Task Force: The Supply and Access for Everyone (SAFE) Task Force has been created by the International Patient Organisation for Primary Immunodeficiencies (IPOPI) to monitor plasma collection and the availability of immunoglobulin replacement therapies for patients with PIDs worldwide. The taskforce is composed of experts from different parts of the world and IPOPI staff (in alphabetical order): Ms Roberta Anido de Pena, Ms Jose Drabwell, Dr Nahla Ewra, Prof Stephen Jolles, Dr Nizar Mahlaoui, Ms Martine Pergent, Mr Johan Prevot, Prof John Seymour, Prof Surjit Singh, Ms Leire Solis.

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