

20 June 2023

#### **ASX ANNOUNCEMENT**

# IMPEDIMED ANNOUNCES THIRD MEDICAL POLICY COVERING SOZO TESTING FOR CANCER PATIENTS AT RISK FOR LYMPHOEDEMA

ImpediMed Limited (ASX.IPD) is pleased to announce the third published medical policy covering BIS testing since the update to the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Survivorship on 23 March 2023. The bioimpedance spectroscopy (BIS)-only policy, published by Blue Cross Blue Shield of Tennessee, covers testing using ImpediMed's SOZO® Digital Health Platform (SOZO) for cancer patients at risk for limb lymphoedema.

## **Key Points**

- Blue Cross Blue Shield of Tennessee<sup>1</sup> (BCBS Tennessee) published the first BIS-only medical policy covering testing using SOZO for cancer patients at risk for limb lymphoedema.
- BCBS Tennessee revised an existing BIS-only policy that previously stated use of BIS was investigational:
  - This provides a template for other large, national payors with existing experimental/ investigational BIS-only medical policies.
  - There are now three different published approaches to medical policies to cover use of BIS testing for patients at risk of lymphoedema, which shows the sense of urgency to integrate BIS into medical policy and provides other Payors with multiple options.
- The policy specifically names SOZO and L-Dex® and identifies BIS as medically necessary when medical appropriateness criteria are met.
- The policy outlines medical appropriateness criteria, which are based on the NCCN Guidelines®
  for Survivorship and include all cancers whose treatment puts patients at risk for limb
  lymphoedema.
- This policy is expected to support the Private Payor payment and testing protocol assumptions used in customer return on investment (ROI) models for SOZO.

The amended medical policy, titled *Bioimpedance Devices for Detection of Lymphedema*, was published online on 19 June 2023 with an effective date of 30 August 2023.

A link to the medical policy may be found here:

https://www.bcbst.com/UpcomingMPs/Topics 08 30 23/Bioimpedance Devices POL.pdf

# **Reimbursement Strategy**

- Large regional Payors, like BCBS Tennessee, are a key step in gaining broad national coverage and this published medical policy continues the domino effect we expect to see in the coming weeks and months.
  - BCBS Tennessee is the second of the 34 BCBS companies to publish a medical policy covering BIS testing.

<sup>&</sup>lt;sup>1</sup> Blue Cross Blue Shield - Tennessee is the top Regional Payor in Tennessee with over 2 million members.



- Since BCBS Tennessee is part of the BCBS Association of 34 BCBS companies, it has the potential
  to impact positive medical policy decisions by other BCBS companies, which collectively insure 1
  in 3 Americans.
- The Company projects nearly 50% of Private Payors to publish coverage by the end of the calendar year 2023 and nearly all Private Payors to publish coverage by the end of the fiscal year 2024.<sup>2</sup>
- With the momentum of payor updates continuing to build, the Company will, at a minimum, announce material policy changes in line with its reimbursement strategy.

Commenting on the new published medical policy, ImpediMed Managing Director and Chief Executive Officer, Richard Valencia said, "We continue to see strong momentum in reimbursement coverage for our BIS technology driven by the recent updates to the NCCN Guidelines for Survivorship. We are seeing the Payors acting with a sense of urgency to expand coverage for BIS testing and establish our technology as standard of care. With the recent capital raise, we can now invest the necessary resources to grow our business and broaden adoption of SOZO to benefit even more patients."

Approved for release by the Managing Director & CEO, Richard Valencia.

## **Contact Details**

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## **About Blue Cross Blue Shield**

- For more than 90 years, Blue Cross and Blue Shield companies have provided quality health care coverage to people in communities across the United States.
- BCBS is an association of 34 independent and locally operated BCBS companies, covering approximately 115 million people, equivalent to 1 in 3 Americans<sup>3</sup>.
- BCBS contracts with more than 1.8 million doctors and hospitals across the U.S.<sup>3</sup>

<sup>&</sup>lt;sup>2</sup> Projected timing based on a combination of direct correspondence from private payors to ImpediMed or to our provider partners, as well as publicly available BIS medical policy publishing updates.

<sup>&</sup>lt;sup>3</sup> Blue Facts Sheet 2023: https://www.bcbs.com/sites/default/files/file-attachments/page/Blue Facts Sheet-2023.pdf



#### About ImpediMed

Founded and headquartered in Brisbane, Australia with US and European operations, ImpediMed is a medical technology company that uses bioimpedance spectroscopy (BIS) technology to generate powerful data to maximise patient health. ImpediMed produces the SOZO® Digital Health Platform, which is FDA-cleared, CE-marked, and ARTG-listed for multiple indications, including lymphoedema, heart failure, and protein calorie malnutrition and sold in select markets globally.

In March 2023, the NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®) for Survivorship were updated and reference bioimpedance spectroscopy as the recommended objective tool to screen atrisk cancer patients for early signs of lymphoedema. With the SOZO Digital Health Platform and L-Dex®, ImpediMed is the only company to offer FDA-cleared technology that uses bioimpedance spectroscopy for the clinical assessment of lymphoedema. The connected digital health platform and large, attractive cancerrelated lymphoedema market present an opportunity for continued strong growth through ImpediMed's SaaS subscription-based business.

For more information, visit <u>www.impedimed.com.</u>

# **Forward-Looking Statements**

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to expand sales and market acceptance in the US and Australia including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialise new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. ImpediMed does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. ImpediMed may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.