



Australian Government
Department of Health

Independence
AUSTRALIA

Eligibility Guidelines

**National Epidermolysis Bullosa
Dressing Scheme**



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1. About this document

Background

The National Epidermolysis Bullosa Dressing Scheme (NEBDS or the Scheme) Eligibility Guidelines provides guidance in relation to the assessment of applications, from or on behalf of people with Epidermolysis Bullosa (EB), to receive subsidised products and other support available under the NEBDS.

Audience/Purpose of this document

This document outlines the criteria to be used by Independence Australia (IA) and the Clinical Advisory Committee (CAC) when assessing applications for eligibility under the Scheme prior to obtaining approval by the Department of Health (the Department). This document also provides information relating to the roles and responsibilities of IA and the Department during the application process.

Audience (project role)	Purpose of the Eligibility Guidelines
Applicants to the Scheme	Documents the roles and responsibilities of the Applicants during the application process.
IA - responsible for administering the Scheme, assessing applications, delivering products and providing secretariat support to the CAC on behalf of the Department.	Documents the roles and responsibilities of IA when receiving, processing, assessing and recommending applications and details the criteria to be used when accessing applications.
CAC - responsible for making recommendations to the Department through IA	Documents the roles and responsibilities of the CAC during the application process, including the assessment of some applications and providing recommendation on those applications.
The Department - responsible for approving all aspects of the Scheme	Documents roles and responsibilities during the application process including the approval/disapproval of applications.

Glossary of Terms common to the Scheme

Term	Abbreviation	Meaning
Applicant of the Scheme	Applicant	A person diagnosed with EB in the process of applying to access the Scheme, and includes such a person's Authorised Representative where the context permits.
Approved Specialist Healthcare Professional (HCP)	Approved Specialist HCP	A Dermatologist, Paediatrician, General Practitioner and Clinical Nurse who is part of a multidisciplinary team specialising in EB and has been approved by the Department as a Specialist HCP for the purposes of the Scheme.
Approved Treating Healthcare Professional	Approved Treating HCP	Dermatologist, Paediatrician, General Practitioner or Clinical Nurse with experience/interest/specialisation in EB and/or wound care who has been approved by the Department as a Treating HCP for the purposes of the Scheme. The current list of Approved HCPs is available from, Independence Australia on 1300 290 400 or email: eb@iagroup.org.au
Authorised Representative	-	A person authorised by a person, and/or the legal guardian of a person, diagnosed with EB, who is able to act on behalf of that person for such things as signing for receipt of a delivery of dressings.
Clinical Advisory Committee	CAC	Committee of health professionals which also includes a consumer representative with expert knowledge, (or people with) skills and experience in inherited bullosa skin disorders, specifically EB.
Eligibility Guidelines	-	Set of criteria recommended by the CAC and approved by the Department, for applications to be assessed against, establishing Applicant eligibility to receive benefits under the Scheme.
Epidermolysis Bullosa	EB	A rare genetic disease primarily affecting children and characterised by extremely fragile and blister prone skin. Management of this disease requires frequent application of specialised dressings and bandages to reduce skin damage and the risk of infection.

Term	Abbreviation	Meaning
Epidermolysis Bullosa Registry	-	A database capturing information required to assess Applicants and supply dressings to Recipients.
National Epidermolysis Bullosa Dressing Scheme	Scheme or NEBDS	The Commonwealth funded program in which the cost of dressings is subsidised for eligible persons diagnosed with Epidermolysis Bullosa. The administration of the Scheme is provided by Independence Australia.
Operational Guidelines	-	A document outlining the tasks and processes required to administer the Scheme.
Recipient of the Scheme	Recipient	An Applicant who is approved to receive benefits from the Scheme, and includes such a persons Authorised Representative, where the context permits.
Schedule	-	A list of approved dressings, bandages and ancillary products subsidised for use by Recipients of the Scheme.
Standard Order	-	A Recipient's order of required dressings which will be used each month unless an amendment is required and approved. The Standard Order is determined by the treating nurse or EB specialist during an Applicant's application process.

Current Version

The latest version of this document has been approved by the Department. Any copies found to be incomplete or obsolete that are not required for historical purposes should be destroyed or returned to the Department.

Public Availability

This document is published on the internet at: www.ebdressings.com.au and www.health.gov.au/ebdressings.

2. Introduction

The Scheme was developed to support better health outcomes for people with EB, a condition characterised by extremely fragile skin, requiring access to specialised bandages, dressings, and ancillary products. Under the Scheme, necessary and clinically appropriate dressings are made more affordable and are provided to persons diagnosed with EB in accordance with clinical guidelines.

Administrative and operational support for the Scheme is provided by IA. The CAC was established on 21 November 2009 to provide clinically-based recommendations to the Department via IA on Applicant eligibility.

3. Application Process

A formal application procedure is necessary to determine eligibility against certain criteria set out in this document. Certain information must be completed before an application will be considered. Once the application form is complete with all available supporting documentation, it should be sent to Independence Australia (IA).

All Applicants and their Approved HCPs will receive confirmation on their acceptance or non-acceptance to the Scheme by return mail. Application forms that are incomplete or where an Applicant's eligibility is unclear may take longer to finalise.

IA will assess each application against the eligibility criteria described in these guidelines and make an appropriate recommendation to the Department. If successful, a Standard Order will be arranged by IA with a regular delivery on a monthly basis.

In the event that IA cannot clearly determine if an Applicant is within the criteria of the Eligibility Guidelines it will:

- facilitate a recommendation by an appropriate representation of the CAC (or sub-committee), as described Section 7 of these guidelines, and
- provide a summary of the deliberations and recommendations of the appropriate representation of the CAC to the Department for approval.

4. Application Form

An Application Form must be completed to document the Applicant's condition. This form assists in the assessment of the Applicant against the agreed criteria and notes the conditions an Applicant must accept to be part of the Scheme. The Application Form must be completed with all details requested. See Appendix 1 for the Application Form.

Section 1 - Applicant's Particulars

This section is to be completed by (or on behalf of) a person who has, or is suspected of having, EB (the Applicant). The Applicant's particulars are required including:

- personal details;
- Medicare number;
- contact details;
- a photocopy of both sides of a Concession Card (if applicable);
- delivery details for dressings if the application is approved; and
- applicant consent and declaration.

Applicant Consent and Declaration

By signing and submitting the Application Form, the Applicant agrees to the Terms and Conditions of the Scheme (see Section 9).

An Applicant's responsibilities under the Scheme are detailed in Section 8 of this document.

Section 2 - Health Referral

This section is to be filled in by the referring EB specialist, as an Approved HCP, who must have read and be familiar with the Eligibility Guidelines. The referring EB specialist must note how the EB diagnosis has been made. Explanations and diagnostic tests must be provided to support any clinical diagnosis which has been made. If the tests are not available, there are provisions to give reasons and the expected date for results. A HCP declaration is required.

Section 3 - Dressings

This section is to be filled in by the treating nurse or EB specialist and will not form part of the assessment of the Application. It establishes the dressing requirements of the Recipient to facilitate prompt delivery of the first Standard Order. This section represents the best estimate of monthly requirements for the Applicant.

Applicants, Recipients and Treating HCPs may include additional dressings and products not listed on the Schedule of Dressings. However, only products listed on the Schedule will be subsidised under the Scheme. A HCP declaration is required and the completed Application Form (all sections) should be sent by mail, fax or email to the NEBDS Administrator at Independence Australia.

The NEBDS Administrator can be contacted during business hours as follows:

Phone: 1300 290 400
Fax: 1 1300 793 132
Email: eb@iagroup.org.au

Mail can be sent to:

c/o - Independence Australia
Attention: NEBDS Administrator
Building 1, 9 Ashley Street
West Footscray VIC 3012

Diagnostic test results that do not accompany the original Application Form must be sent to Independence Australia by mail, fax or email as soon as these results are available. The test results must clearly identify the Applicant and referring Specialist HCP.

Any incomplete forms will be returned to the Applicant or Approved HCP to complete the relevant Section.

5. Applicant Eligibility Criteria

- Applicants are eligible to apply to access subsidised products available under the Scheme if they have Simplex, Junctional, Dystrophic and Kindler EB, or their subtypes, are Medicare eligible and are referred by a Specialist HCP approved under the NEBDS.
- The Application Form must be duly completed including Applicant's Particulars, Applicant Consent and Declaration, Specialist HCP Referral, Dressing Requirements, and HCP Declaration.
- Applicants must provide proof of diagnosis by way of a:
 - confirmatory test report from a genetic testing following consultation with a geneticist; or
 - confirmatory test report from a skin biopsy (Immunofluorescence Antigenic Mapping - IFM and/or Transmission Electron Microscopy - TEM); or
 - clinical diagnosis by an Approved Specialist HCP or a multidisciplinary EB clinic.
 - If the Applicant is a newborn suspected of having EB, provisional access to the Scheme will be given for six (6) months. A confirmatory diagnosis must be submitted three (3) months following the approval of the original application for the Applicant to continue on the Scheme.

Terms and conditions apply (see Section 9).

6. Reviews

Review of Recipient

Recipients who are approved to receive assistance through the Scheme are strongly encouraged to regularly meet with their Approved Treating HCP for clinical review.

This is to ensure that the Recipient's condition is being managed and the dressings subsidised through the Scheme are used in accordance with best clinical practice for the management of EB.

Review of Recipient's Dressing Order

The Recipient review will also enable the Approved Treating HCP to review the Standard Order of dressings in line with a Recipient's clinical requirements.

The dressing requirements of a Recipient under the Scheme may change from time to time due to growth (age), change in condition or impact of seasonal changes. Scheme Recipients are encouraged to regularly follow up with their treating HCP for advice and assistance on how to best manage their condition.

If existing dressing requirements established for a Recipient are no longer appropriate, s/he can apply to change/update the dressing requirements. Section 3 of the Application Form must be completed by an Approved Specialist or Treating HCP to establish the new dressing requirements for the Recipient.

Once completed, Section 3 of the Application Form should be sent to IA via email, fax or mail:

Email: eb@iagroup.org.au
Fax: 1300 793 132
Mail: c/o – Independence Australia
Attention: NEBDS Administrator
Building 1, 9 Ashley Street
West Footscray VIC 3012

Incomplete forms will be returned to the Applicant or the referring HCP for completion.

7. Role of the Clinical Advisory Committee (CAC)

If an application is not clearly within the eligibility criteria using the Eligibility Guidelines, the application will be submitted to the CAC, or a representation of the CAC, for assessment.

CAC members are nominated to review individual applications, as facilitated through IA. Any Conflicts of Interest, including application assessments by a CAC member who is the Applicant's Approved HCP, will be considered when nominating the CAC member to assess the application.

8. Roles and Responsibilities

Applicant / Applicant's Authorised Representative

- Complete relevant section and Applicant Consent and Declaration on the Application Form;
- Request their Approved Specialist HCP to complete and submit the form to IA with all necessary documentation (where applicable); and
- If access to the Scheme is approved, adhere to the Terms and Conditions of the Scheme (see Section 9) and promptly inform IA of any changes to personal details, circumstances or eligibility status.

Approved Specialist Healthcare Professional

1. Make an assessment of the Applicant's condition;
2. Complete relevant section/s of the Application Form, providing all required supporting information/documents as appropriate;
3. Assist the Applicant, as appropriate, in completing the Application Form.
4. Submit the completed Application Form, on the Applicant's behalf, to the IA; and
5. Receive a copy of the written response to the application.

Approved Treating Healthcare Professional

1. Assess the Applicant's dressings need and recommend necessary dressings;
2. Complete relevant section/s and HCP Declaration on the forms,
3. Assist the Applicant, as appropriate, in completing the Application Form.
4. Educate Recipient on appropriate usage of dressings, bandages and ancillary products.
5. Submit the Application Form and completed Dressings Requirements (Section 3 of the Application Form), on the Applicant's behalf, to IA; and
6. Receive a copy of the written response to the application.

Independence Australia

1. Maintain and distribute Application Forms to relevant HCPs and clinics;
2. Provide a point-of-contact for potential Applicants (and their representatives and HCPs) seeking information about and/or intending to apply to the Scheme;
3. Respond to Applicant and HCP queries regarding the Scheme and the application process.
4. Assist in the completion and submission of the application forms.
5. Check each application form for completeness, evaluate against the eligibility criteria

and:

- provide the Department with a recommendation of the Applicant's eligibility to the Scheme, OR
 - for Applicants who are not clearly within the eligibility criteria of the Scheme, send the application to the CAC panel or subcommittee for further clarification on eligibility, and then
 - forward recommendations from the CAC panel or subcommittee on Applicant's eligibility status to the Department for final approval.
6. Maintain an efficient system to facilitate, prioritise and process applications and store Applicant and Recipient information.
 7. Communicate the Department's decision directly to the Applicant/Recipient and the referring HCP on the outcome of the application.
 8. Arrange an initial Standard Order for an Applicant when his/her application is approved, and in consultation with the Applicant or the Authorised Representative make arrangements for subsequent ongoing orders;
 9. Confirm orders with the Recipients (or, their Authorised Representatives) prior to delivery, collect relevant co-payments and ensure orders are delivered in full and on time; and Submit appropriate invoices to the Department for reimbursement for dressings supplied.

Clinical Advisory Committee

1. Provide clinical advice to establish the Eligibility Guidelines.
2. For those Applicants who are not clearly within the Eligibility Guidelines (inclusionary or exclusionary), provide a clinical recommendation on the application. A panel or subcommittee may be formed to conduct this activity
3. Propose a list of appropriate dressings, bandages and ancillary items to be subsidised and develop clinical guidelines for dressing usage by recipients according to International best practice.
4. Meet at least annually to provide recommendations to the Department about the Scheme, including periodic reviews of dressings for subsidy on the Scheme and their suitability for use by people with EB.

9. Terms and Conditions

In addition to the aforementioned roles and responsibilities, Applicants and Authorised Persons are required to adhere to these Terms and Conditions in order to maintain eligibility to the Scheme. Recipients or Authorised Persons are also required to comply with the delivery and co-contributions of the Scheme as outlined in the National EB Dressing Scheme booklet.

Applicants or Authorised Persons must provide all the information relating to Section 1 of the Application Form and make necessary arrangements, with the appropriate Approved HCP, to complete the remaining Sections. Any costs associated with completing an Application Form, whether the Applicant is successful or not, will be borne by the Applicant or Authorised Person. These costs may include appointments and consultations, completion of the remaining Sections of the form by a HCP, diagnostic testing, access to past medical records, and any other costs required to confirm eligibility to the Scheme.

Recipients or Authorised Persons agree to advise IA of:

- Change of name,
- Change of address,

- Hospitalisation, within 72 hours of admission,
- Non-delivery of dressing products within 48 hours,
- Change to Concessional Card status (with evidence)

Furthermore, Applicants or Authorised Persons agree to:

- Complete Section 1 of the Application Form prior to passing the form onto the Approved HCP,
- Co-contributions at the time of ordering,
- Using dressings according to the instructions of the Treating HCP*.
- Making appointments with their Treating HCP for advice and assistance on how to best manage their condition.
- Having their personal information collected for the purpose of the Scheme,
- Providing the correct address for delivery where a signatory must be available during business hours,
- Ensuring IA is accurately informed (at time of order confirmation) each month of:
 - the dressings required, or not required, that month that are within the allowable limits**, and,
 - if an extended hospital stay*** has taken place.
- Store dressings appropriately, according to manufacturer's recommendations.

* Apply dressings as instructed by the Treating HCP.

** The maximum allowable limit for dressings is established by the Treating HCP for each individual, based on "Section 3 – Dressing Requirements" of the Application Form. Any change to a Standard Order requested by a Treating HCP will be actioned on a NEBDS Application Form Section 3.

*** An extended hospital stay is a stay that is equivalent to, or more than, one (1) month duration. If an extended hospital stay has taken place, a pro rata quota of dressings will apply.

10. Confidentiality

IA and the CAC may be provided with confidential material. This information must not be disclosed to anyone outside the CAC, IA, or members of the Department involved in the implementation of the Scheme.

All material associated with the Scheme must be treated and stored with the utmost care, discretion and in accordance with the Privacy Act 1988. (See page 2 of the Application Form "Privacy and Your Personal Information").

11. Ethical Conduct

Unbiased Assessment

All applications will be assessed against the criteria as indicated in these Eligibility Guidelines. Any unclear applications will be forwarded to the CAC for expert opinion and recommendation regarding eligibility. Final approval will be made by the Department.

Appropriate use of information

Information provided by the Applicant will be used only for the purposes of the Scheme. This includes HCPs who are involved with assessing, processing, reviewing and finalising an application. All information will be treated and stored in accordance with the Privacy Act 1988.

12. Conflict of Interest

Conflict of interest is defined as any instance where a staff member, contractor, partner/family member or close family friend has a direct financial or other interest which influences, or may appear to influence, proper consideration or decision-making involved with the Scheme, including the Application process for individuals. This definition also applies to CAC members, involved staff of IA, and members of the Department who are involved with the Application process.

Appendix 1 - Application Form

To download this form visit www.ebdressings.com.au/forms



Australian Government
Department of Health

National Epidermolysis Bullosa Dressing Scheme (NEBDS) Application Form

About NEBDS: NEBDS aims to support better health outcomes for people with Epidermolysis Bullosa (EB) by improving access to subsidised dressings, bandages and ancillary products used in the management of their chronic conditions. The Scheme is funded by the Australian Government.

Eligibility to NEBDS: Australians (citizens and permanent residents) who have Simplex/Junctional/Dystrophic/Kindler EB or their subtypes, are Medicare eligible and are referred by a Specialist Health Care Professional (HCP) approved under the NEBDS, are able to access products listed on the NEBDS Schedule under subsidy.

Assistance and Information: For assistance or information (e.g. list of approved Specialist HCPs, NEBDS Schedule and Eligibility Guidelines), please contact the NEBDS Administrator, on 1300 290 400 or email: eb@iagroup.org.au

Lodgment of Application:

- ▶ **For new applicants,** complete all sections (Section 1, 2 and 3) of this form.
- ▶ **For current NEBDS recipients,** only complete Section 3 of this form.

Once completed, the form and any supporting documents (e.g. copy of Medicare card, Health Care card, biopsy/diagnosis/test reports) should be sent to the NEBDS Administrator via email, fax or mail:

Email: eb@iagroup.org.au **Fax:** 1300 793 132

Mail: NEBDS Administrator, c/o - Independence Australia, Building 1, 9 Ashley Street, West Footscray VIC 3012

- **Please complete this form using a black or blue pen.**
- **For current recipients under NEBDS, complete Section 3 only.**

SECTION 1 - Applicant's Particulars

1 Mr Mrs Miss Ms Other

Family name

Given names

2 Date of birth (dd/mm/yyyy) / /

3 Sex: Male Female Intersex
Indeterminate or Unspecified

4 Medicare number
 /
Valid to (mm/yyyy) /

5 Are you of Aboriginal or Torres Strait Islander Australian descent (Question 5 is optional)?
Yes No

6 Your contact details

Phone number ()

Alternative phone number ()

Email

7 Your address

Permanent address

Suburb

State

Postcode

Postal/delivery address

Suburb

State

Postcode

8 Do you have a valid concession card from the following list:

- Health Care Card
- Pensioner Concession Card
- Commonwealth Seniors Health Card
- DVA White, Orange, or Gold Card

Authorised Representative

9 If you have or wish to nominate an Authorised Representative to act on and/or communicate on your behalf, please provide the details of the person:

Name
Phone number ()
Alternative phone number ()
Email
Relationship to the Applicant

Orders and Delivery

10 Will you or your Authorised Representative be able to confirm your orders?

Yes No

11 Will someone be available at your delivery address, during business hours, to receive the delivery of your orders?

Yes No

Privacy and Your Personal Information

- Personal information is protected by law, including the *Privacy Act 1988*, and is being collected on this form by the NEBDS Administrator on behalf of the Australian Government Department of Health (Department) to:
 - (a) determine the applicant's eligibility to receive subsidised products and other support under the NEBDS; and
 - (b) provide products and support available under the NEBDS to an approved applicant.
- If the information requested in this form is not provided, the Department may not have the necessary details to make a decision on the applicant's eligibility for NEBDS and/or provide the products and support available under NEBDS.
- You can get more information about the way in which the NEBDS Administrator and the Department will manage your personal information, including the respective privacy policies at: <https://www.ebdressings.com.au/privacy>; and <http://www.health.gov.au/internet/main/publishing.nsf/Content/eb-dressing-1#patients>

Applicant Consent and Declaration

- I am the applicant or the Authorised Representative of the applicant applying for access to the NEBDS;
- I consent to the Department collecting and disclosing, as necessary, personal information provided in this form for the purpose of determining the applicant's eligibility for NEBDS and, if approved, providing products and support available under NEBDS; and
- If this application is approved, I agree to adhere to the terms and conditions of NEBDS as outlined in the *National Epidermolysis Bullosa Dressing Scheme Eligibility Guidelines*.

Signature

Date

SECTION 2 - Specialist HCP Referral

This section of the form must be completed by a Specialist HCP approved under the NEBDS.

12

13

14 Diagnosis

The applicant has a diagnosed condition of:

Dystrophic EB EB Simplex

Junctional EB Kindler Syndrome

EB Subtype _____

15 Method of Diagnosis

- Skin biopsy (attach biopsy report)
 - Genetic test (attach test report)
 - Clinical diagnosis (provide brief explanation)
- _____
- _____

16 Recommended Clinical Follow Up Intervals

3 6 9 12 months

17 Health Professional Details

Dr Assoc. Prof Professor

Name

Provider number

Signature

Date

Appendix 2 - Eligibility Checklist

1.	Has a clinical diagnosis been made by an Approved Healthcare Professional? Refer to the NEBDS Administrator at IA (contact details on page 6) for the current list.
2.	Has a diagnostic test* to confirm clinical diagnosis and confirmation of EB subtype commenced? - complete the details in Section 2 of the Application Form
3.	Does the diagnostic test consist of a skin biopsy? (Note the expected time for results to be completed by and sent to the NEBDS Administrator). The details in Section 2 of the Application Form must be completed.
4.	Is the diagnosis by way of: <ul style="list-style-type: none"> • Immunofluorescence mapping; or • Transmission electron microscopy; or • Genetic testing?
5.	Proceed to complete Section 2 of the Application Form and sign the declaration.
6.	Forward the Application Form to the treating Nurse or EB expert to complete Section 3 of the Application Form.

* Note that a diagnostic test consists of a skin biopsy that must be undertaken using immunofluorescence mapping, transmission electron microscopy or genetic testing.