



Australian Government

Department of Health and Ageing

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AUSTRALIA

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# National Epidermolysis Bullosa Dressing Scheme

## Eligibility Guidelines

September 2012

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## 1. About this document

### Background

The National Epidermolysis Bullosa Dressing Scheme (NEBDS or the Scheme) Eligibility Guidelines outline the criteria recommended by the Clinical Advisory Committee (CAC) with which to assess applicants' eligibility to receive benefits under the Scheme.

### Audience/Purpose of this document

This document outlines the criteria to be used by BrightSky Australia (BrightSky) and the CAC when assessing applications for eligibility under the Scheme prior to obtaining approval by the Department of Health and Ageing (the Department).

This document also provides information relating to the roles and responsibilities of BrightSky 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.
BrightSky – 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 BrightSky 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 BrightSky	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
National Epidermolysis Bullosa Dressing Scheme	Scheme	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 BrightSky Australia.
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.
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.
Patient of the Scheme	Patient	An Applicant who is approved to receive benefits from the Scheme, and includes such a person's Authorised Representative where the context permits.
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 with expert knowledge, (or people with) skills and experience in inherited bullosa skin disorders, specifically EB.
Clinical Advisory Subcommittee	-	CAC may form a subcommittee, with representation as described by the CAC, to assess and recommend the eligibility of some Applicants out of session.
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.
Clinical Guidelines	-	Best international practice guidelines recommended by the CAC and approved by the Department, suggesting correct application and use of the subsidised dressings.
Schedule of Dressings	-	A list of approved dressings subsidised for use by Patients of the Scheme.

Operational Guidelines	-	A document outlining the tasks and processes required to administer the Scheme.
Patient Registry	-	A database capturing information required to assess Applicants and supply dressings to Patients.
Standard Order	-	A Patient'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.
Approved Healthcare Professional	-	A healthcare professional (specialist) with expert knowledge, skills and experience in inherited bullosa skin disorders, specifically EB. The current list of Approved Healthcare Professionals is available from, BrightSky Australia on 1 300 290 400 or email: <a href="mailto:eb@brightsky.com.au">eb@brightsky.com.au</a>
Treating Healthcare Professional	-	An Approved Healthcare Professional or a nurse with experience in managing the treatment of EB.

### 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](http://www.ebdressings.com.au) and [www.health.gov.au/ebdressings](http://www.health.gov.au/ebdressings)

## **2. Introduction**

The Scheme was developed to support people most in need with epidermolysis bullosa (EB), a condition characterised by extremely fragile skin, requiring access to specialised bandages and dressings. Under the Scheme, necessary and clinically appropriate dressings are made more affordable and are provided to persons diagnosed with EB in accordance with international best practice guidelines.

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

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

BrightSky 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 BrightSky with a regular delivery on a monthly basis

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

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

A schematic representation of the process is set out under Section 8.

## **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 filled in by (or on behalf of) a person who has, or is suspected of having epidermolysis bullosa (the Applicant). The Applicant's particulars are required including:

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

## **Applicant Declaration**

By signing and submitting the Application Form, the Applicant agrees to the Terms and Conditions of the Scheme.

An Applicant's responsibilities under the Scheme are detailed in Section 9 of this document.

## **Section 2 – Health Report**

This section is to be filled in by the referring EB specialist, as an Approved Healthcare Professional, who must have read and be familiar with the NEBDS 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 healthcare professional 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 Patient to facilitate prompt delivery of the first Standard Order. This section represents the best estimate of monthly requirements for the Applicant.

Applicants, Patients and Treating Health Care Professionals may include additional dressings and products not listed on the Schedule of Dressings. However, only products listed on the Schedule of Dressings will be subsidised under the Scheme.

A healthcare professional declaration is required and the completed Application form (all sections) should be sent by mail, fax or email to the NEBDS Administrator at BrightSky.

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

Phone: 1300 290 400  
Fax: 1300 886 602  
Email: [eb@brightsky.com.au](mailto:eb@brightsky.com.au)

Mail can be sent to:

c/- BrightSky Australia  
Attention: NEBDS Administrator  
P.O. Box 6347  
Silverwater DC NSW 1811

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

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

## 5. Patient Eligibility Criteria

Patients with all subtypes of Simplex, Junctional, Dystrophic and Kindler EB are eligible to access dressings through the Scheme.

Proof of diagnosis by way of diagnostic testing from an Approved Healthcare Professional is required.

These Eligibility Guidelines aim to provide clear criteria based on the presenting medical condition(s).

### Diagnostic method and results for all sub types

For the purposes of the Scheme, an initial clinical diagnosis is required by an Approved Healthcare Professional. (A list of Approved Healthcare Professionals is available from the NEBDS Administrator at BrightSky who can be contacted on 1300 290 400).

The clinical diagnosis is followed by a skin biopsy with immunofluorescence mapping, transmission electron microscopy or genetic testing within six (6) months of application. In the case of newborns, **confirmatory diagnosis must be provided within three (3) months of application.**

New applicants may provide the genetic results of a family member as supporting evidence for their own clinical diagnosis. This evidence must clearly state the diagnosis and subtype of EB for the family member. Sufficient evidence of family relationship (including birth certificates) and probability of inheritance must also be supplied.



## **6. Patient Reviews**

### **Review of Eligibility**

Patients who are approved to receive assistance through the Scheme are required to regularly meet with their Approved Treating Healthcare Professional for clinical review. The timeframe, stated by the Approved Treating Healthcare Professional, will be indicated on the application form and must be at least once every 12 months.

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

BrightSky will monitor the review period and remind Patients of when reviews are pending. Patients are required to attend their review at the nominated interval, unless otherwise informed by the Approved Treating Healthcare Professional. Patients not in compliance with this requirement risk being removed from the Scheme.

### **Review of Patient's Dressing Order**

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

If the Patient's condition has changed or their dressing requirements change, an updated Dressing Order Form will be required to be sent on the NEBDS Review Form.

## **7. Role of the Clinical Advisory Committee**

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 BrightSky Australia. Any conflicts of Interest, including application assessments by a CAC member who is the Applicant's Approved Health Professional, will be considered when nominating the CAC member to assess the application.

## **8. Roles and Responsibilities**

### **Approved Healthcare Professional**

1. Complete Section 2 (and possibly Section 3) of the application form, providing all required supporting information.
2. Assist the Applicant in completing the application form.
3. Receive a copy of the written response to the application.

### **Approved Treating Healthcare Professional**

1. Complete Section 3 of the application form, providing all required supporting information
2. Assist the Applicant in completing the application form.
3. Recommend necessary dressings (from the Approved Dressing List) for the patient as part of the clinical requirements on the form.
4. Support international best practice by working with patients to educate on dressing usage.
5. Submit the application form to BrightSky, on behalf of the Patient and await a written response.
6. Receive a copy of the written response to the application.

### **BrightSky Australia**

1. Respond to Applicant and healthcare professionals queries regarding the application process.
2. Assist in the completion and submission of the application forms.
3. 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.
4. Maintain the Patient Registry.
5. Communicate the Department's decision directly to the Applicants on their inclusion/exclusion from the Scheme.
6. Send a copy of the Department's decision to the referring healthcare professionals who have completed Sections 2 and 3 of the Application Form.
7. Set up order arrangements as per the Operational Guidelines and check with the Applicant or Authorised Representative, arrangements for ongoing or subsequent orders.
8. Deliver the first dressing order to Patients.
9. Send the appropriate dressings to Patients each month.
10. Invoice the Department for dressings issued.

### **CAC**

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 to be subsidised and develop clinical guidelines for dressing usage by patients according to International best practice.
4. Meet at least annually to provide recommendations to the Commonwealth about the Scheme, including periodic reviews of dressings for subsidy on the Scheme and their suitability of dressing for use by EB patients.

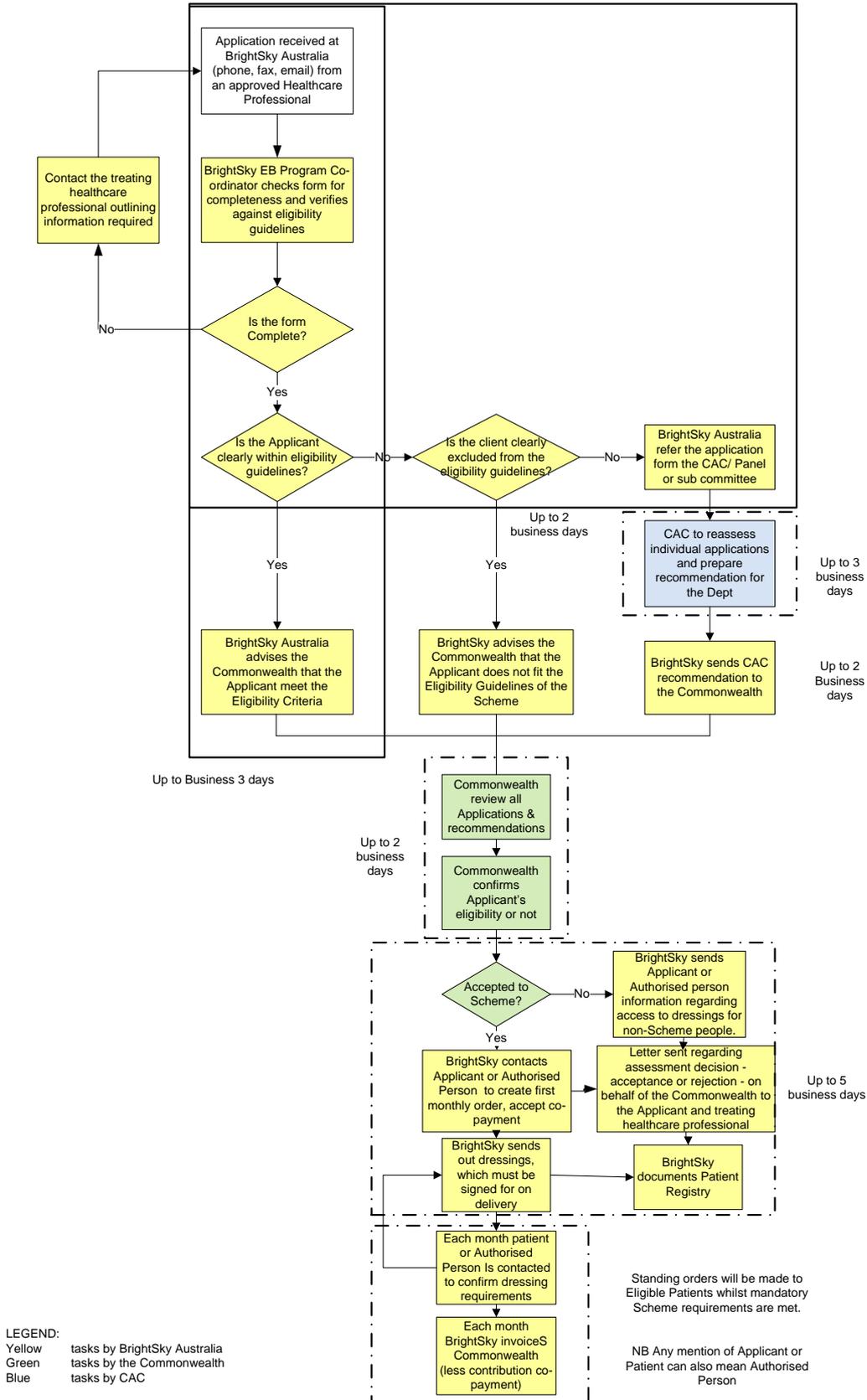
### **The Department**

1. Review all applications and advise BrightSky if the Applicant will be admitted to the Scheme (to become a Patient of the Scheme).
2. Meet the remaining costs (after patient contributions) of the supply of dressings.

### **Applicant / Patient / Authorised Representative of the Scheme**

1. Complete appropriate fields on the Application Form and agree to the Terms and Conditions of the Scheme.
2. Request that the Approved Healthcare professional complete and submit the form to BrightSky with all necessary documentation (where applicable).
3. Once eligible, adhere to all Terms and Conditions of the Scheme and ensure BrightSky are informed of any changes to personal details or eligibility status.

# OPERATIONAL GUIDELINES ON ACCESS TO THE SCHEME & OBTAINING DRESSINGS



## 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. Patients 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 Healthcare Professional, 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 Healthcare Professional, diagnostic testing, access to past medical records, and any other costs required to confirm eligibility to the Scheme.

Patients or Authorised Persons agree to advise BrightSky 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, Patients or Authorised Persons agree to:

- Complete Section 1 of the Application Form prior to passing the form onto the Approved Healthcare Professional,
- Co-contributions at the time of ordering,
- Using dressings according to the Treating Healthcare Professional\*.
- Making appointments and attending a regular review with their Treating Healthcare Professional as indicated\*\*,
- 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 BrightSky 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 manufacturers recommendations.

\* Apply dressings as instructed by the Treating HealthCare Professional, or as described at

[http://www.ebdressings.com.au/Approved\\_Dressings/How\\_to\\_use\\_Dressings](http://www.ebdressings.com.au/Approved_Dressings/How_to_use_Dressings).

\*\* Regular reviews with the Treating Healthcare Professional are mandatory. A review must take place at least once every 12 months, or earlier as indicated on the Application Form or subsequently on the NEBDS Review Form.

\*\*\*The maximum allowable limit for dressings is established by the Treating Healthcare Professional for each individual, based on “Section 3 – Dressings” of the Application Form. Any change to a Standard Order requested by a Treating Healthcare Professional will be actioned on a NEBDS Review Form, and the form will indicate a next review date indicated by the Approved Healthcare Professional.

\*\*\*\* 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**

BrightSky and the CAC may be provided with confidential material. This information must not be disclosed to anyone outside the CAC, BrightSky, 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*.

## **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 healthcare professionals, the CAC, BrightSky Australia and the Department 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 BrightSky, and members of the Department who are involved with the Application process.

## Appendix 1 – Application Form

## Appendix 2 – Eligibility Checklist

1.	Has a clinical diagnosis has been made by an Approved Healthcare Professional? Refer to the NEBDS Administrator at BrightSky Australia (contact details on page 7) for the current list.
2.	Has a diagnostic test* to confirm clinical diagnosis and confirmation of EB sub-type 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:
	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.