## 

**Prostheses List Management System (PLMS)**

**User Guide – Prosthesis Device Application**

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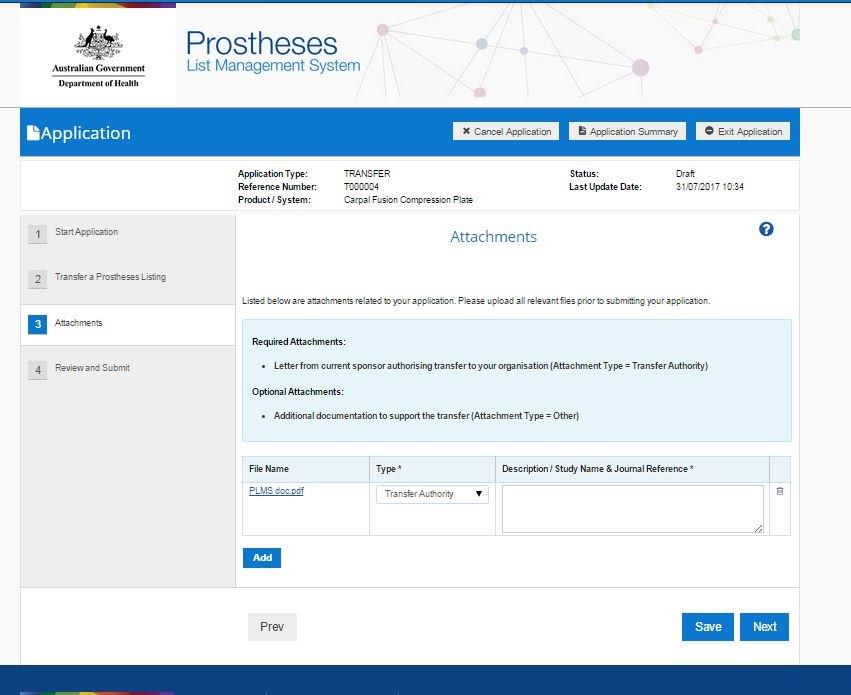
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# Introduction

## About

The Department of Health developed the Prostheses List Management System (PLMS) to streamline the application process for listing a prosthesis device on the Prostheses List. The system allows sponsors and suppliers to create, edit and monitor applications for prostheses listings.

## About this Guide

The purpose of this user guide is to assist sponsors and suppliers in using the Prostheses List Management System (PLMS). Pictures of the screens from the online system are used throughout this guide in order to help navigate between the portal and the guide. These screenshots are to provide a visual representation of the look and feel and are not intended to be read in full.

The **PLMS User Guide – Prosthesis Device Application** will provide guidance on:

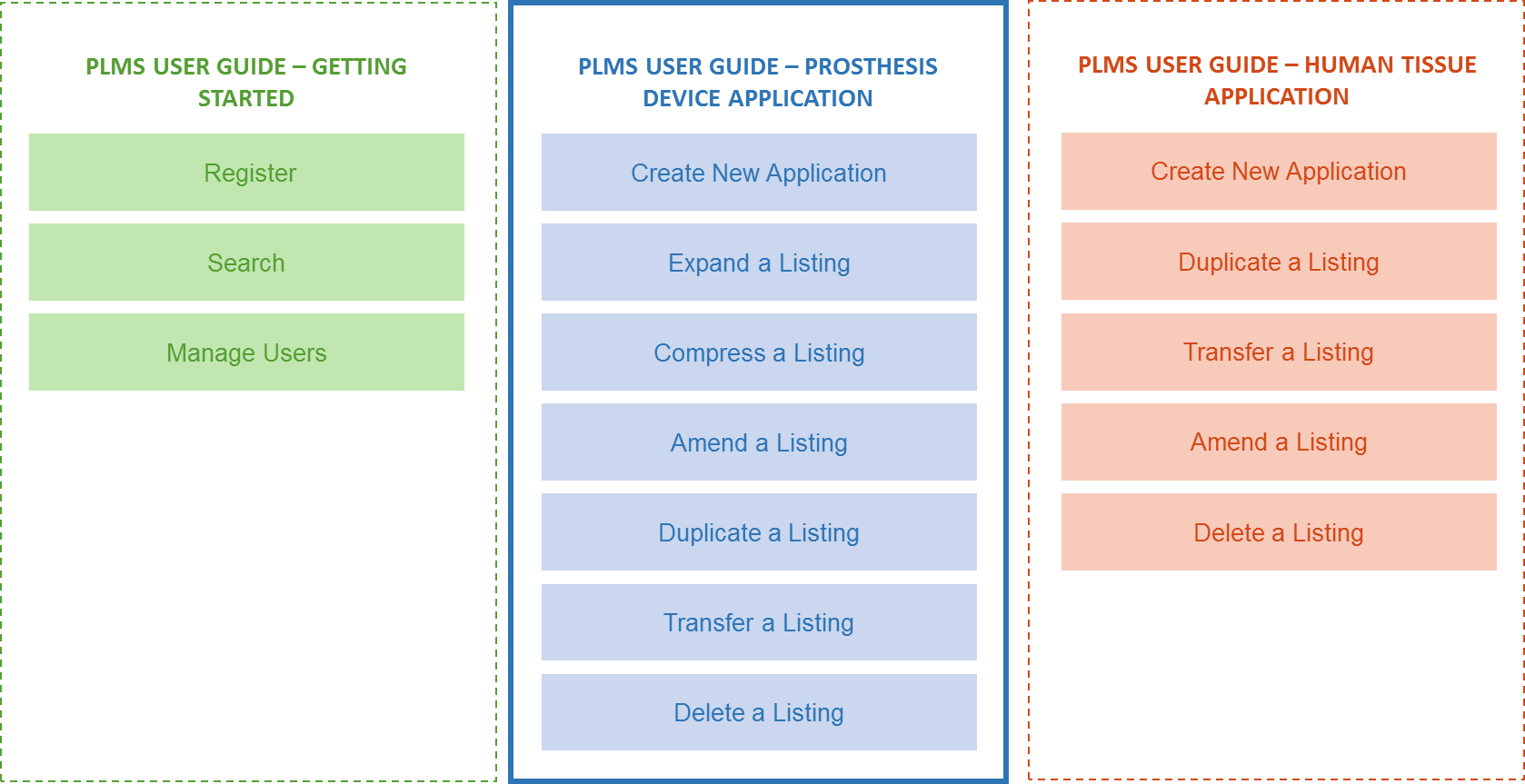
1. Creating a New Application
2. Expanding a Listing
3. Compressing a Listing
4. Amending a Listing
5. Duplicating a Listing
6. Transferring a Listing
7. Deleting a Listing

**If you have any questions about using the Prostheses List Management System, contact the Department of Health at** [**prostheses@health.gov.au**](mailto:prostheses@health.gov.au)

**PLMS User Guides**

There are three user guides available for the PLMS:

* PLMS User Guide – Getting Started
* PLMS User Guide – Prosthesis Device Application
* PLMS User Guide – Human Tissue Application (in development)



# PLMS Home

You can complete a number of actions from the PLMS Home.

|  | Click Create Application to create, expand, compress, duplicate, transfer, amend or delete a listing from the Prostheses List.  Click Search to search applications.  Click Manage Users to manage User Roles (User Administrators only).  Click the C:\Users\hayley.cosgrove\AppData\Local\Microsoft\Windows\INetCache\Content.Word\Note icon (002).jpg icon to view the Application Summary of an application.  Click the C:\Users\hayley.cosgrove\AppData\Local\Microsoft\Windows\INetCache\Content.Word\Edit Icon (002).jpg icon to view and edit an application.  Click Show All to view a list of all of your applications. |
| --- | --- |

# Hints for completing an application

This guide provides help on the functions available to you when completing an application for a prosthesis device.

| **WHAT** | **HELPFUL HINT** |
| --- | --- |
| **Mandatory fields** | Mandatory fields are marked with an asterisk (**\***). These fields need to be completed in order to progress to the next screen |
| **Error messages** | Error messages will appear in red text if information in a field is missing or incorrect. These error messages will appear at the top of the screen, and you will need to scroll to the top of the page to see them |
| **Save** | Click the Save button to save information on a page |
| **Next** | Click the Next button to save information and go to the next page |
| **Previous** | Click the Previous button to go to the previous page. Ensure you save information on the current page by clicking the Save button |
| **Cancel Application** | Click the Cancel Application button to discard your application |
| **Application Summary** | Click the Application Summary button to view a summary of your application |
| **Exit Application** | Click the Exit Application button to leave your application. Ensure you save information on the current page by clicking the Save button |
| **?** | Click on the C:\Users\hayley.cosgrove\AppData\Local\Microsoft\Windows\INetCache\Content.Word\Question mark icon (002).jpg icon to view help text for a page. |

# 1. Create New Application

When you Create a New Application, you are applying to list a new prosthesis device on the Prostheses List.

Before you start an application:

1. Download and read the *Prostheses List – guide to listing and benefits for prostheses:*
   * [Prostheses List Guide](http://www.health.gov.au/internet/main/publishing.nsf/Content/69F6A026037D6093CA257BF0001B5EDA/$File/Prostheses%20List%20Guide%20-%20February%202017.docx)(Word 977 KB)
   * [Prostheses List Guide](http://www.health.gov.au/internet/main/publishing.nsf/Content/69F6A026037D6093CA257BF0001B5EDA/$File/Prostheses%20List%20Guide%20-%20February%202017.pdf)(PDF 502 KB)
2. View the [grouping schemes](http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslistforms) for each category of product, including suffix definitions and benefits.

The steps to Create a New Application are:

| **Create New Application** |
| --- |
| * 1. PLMS Home   2. Start Application   3. Product Summary   4. New Prosthesis Device   5. Comparator(s)   6. Evidence, Benefit and Economic Information for New Grouping\*   7. MBS Item(s)   8. Product Setting and Product Purpose   9. Comparative Clinical Effectiveness   10. Attachments   11. Review and Submit   12. Application Summary |

\* You only need to complete this application step if applicable

# 1.1 PLMS Home

**1. Create New Application**

|  | STEP 1 – Click Create Application on the left of the screen. |
| --- | --- |

# 1.2 Start Application

**1. Create New Application**

| On the Start Application page you have the option to create, expand, compress, duplicate, amend, transfer or delete a listing from the Prostheses List. | APPLICATION TYPE  STEP 1 – Select **Create a New Listing** using the drop down menu.  **APPLICATION CONTACTS**  STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information.  You can add a **Secondary Contact** to your application, if needed.  STEP 3 – To create a **New Contact** for the application:   * Tick the **Create New Contact** box * Enter **First Name**, **Last Name**, **Phone Number(s**) and **Email** address for the contact   The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department. |
| --- | --- |

# 1.3 Product Summary

**1. Create New Application**

|  | **PRODUCT TYPE**  STEP 1 – Click the option for**Prosthesis Device***.*  STEP 2 – Choose **Yes** or **No** to indicate if you are listing a product system.   * If **No**, click Next to go to the next page * If **Yes**, go to STEP 3   *A product system is a prosthesis device made up of two or more components that work together. A product system is clinically assessed as a whole, regardless of the number of parts in the system.*  STEP 3 – If you are applying to list a product system, enter the **Product System Name** in the space provided.  *The product system name is the name the prosthesis is sold under in Australia.* |
| --- | --- |
| 1.3 Product Summary *continued*  **1. Create New Application** | **PRODUCTS SYSTEM COMPONENTS**  STEP 4 – Click Add Product.  When listing a product system, you will need to complete the following sections for each system component:   * **New Prosthesis Device**(1.4 of this guide) * **Comparator(s)**(1.5 of this guide) * **Benefit and Economic Information for New Grouping**(if applicable) (1.6 of this guide)   When you finish adding a system component, it will be listed under the **Products System Components** list.  When naming a product system component, include both the name of the system, and the part (e.g. ACME HIP system – Femoral Head).  *Each system component included in your application will:*   * *Receive a unique billing code* * *Require an initial listing payment fee of $200*   STEP 5– After adding all the system components, click Next.  *You must complete all other sections in the application for the product system as a whole.* |

# 1.4 New Prosthesis Device

**1. Create New Application**

|  | PRoduct Details  STEP 1 – Enter the **Product Name**.  *The product name is the name the prosthesis is sold under in Australia.*  The information you provide for **Product Name** will be available on the Prostheses List should your application be successful.  STEP 2 – Enter a **Description** of the product.  *Describe the prosthesis in one sentence.*  The information you provide for **Description** will be available on the Prostheses List should your application be successful.  STEP 3 – Enter the **Size** of the product.  *Accurately describe the dimensions of the prosthesis or system in one sentence.*  The information you provide for **Size** will be available on the Prostheses List should your application be successful.  STEP 4 – Enter the **Catalogue Number(s).**  *List the catalogue number(s) under which the product is sold in Australia.* |
| --- | --- |
| 1.4 New Prosthesis Device *continued*  **1. Create New Application** | artg id number  STEP 5 – If you have a current ARTG entry(ARTG ID Number)for the product, enter the number into the grey box, and select the correct option from the drop down list.  Once selected, the rest of the table should populate with information.  *An ARTG entry is a number given to products entered and current on the Australian Register of Therapeutic Goods (ARTG).*  *You can find your ARTG entry on the Therapeutic Goods Administration Certificate of Inclusion on the Register.*  STEP 6 – If you have applied to include the product on the ARTG, but the decision is pending, tick the box.  *Only products entered on the ARTG can be listed on the Prostheses List.*  *The Department will progress your Prostheses List application without an ARTG entry, however the product will not be listed on the Prostheses List until the sponsor provides the ARTG entry to the Department.* |

# 1.4 New Prosthesis Device *continued*

**1. Create New Application**

| View the [grouping schemes](http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslistforms) for each category of product, including Suffix definitions and benefits. | Grouping  STEP 7 – Select a **Category** from the drop down menu.  *If the product fits into more than one category, list the category that will represent the greatest use of the product.*  STEP 8 – Select a **Subcategory** from the drop down menu.  STEP 9 – Select a **Group** from the drop down menu.  To add a new Group, click Add, enter the new Group name in the space provided, and click Save.    STEP 10 – Select a **Subgrou**p from the drop down menu, if needed.  To add a new Subgroup, click Add, enter the new Subgroup name in the space provided, and click Save.  STEP 11 – Select a **Suffix** from the drop down menu, if needed.  To add a new Suffix, click Add, enter the new Suffix name in the space provided, and click Save.  If you add a new Group, Subgroup or Suffix, you will have to fill out the Evidence, Benefit and Economic Information for New Grouping section (1.6 of this guide) on your application. If you suggest a new Group, Subgroup or Suffix, the Department will review your evidence and either accept or decline your suggestion. |
| --- | --- |

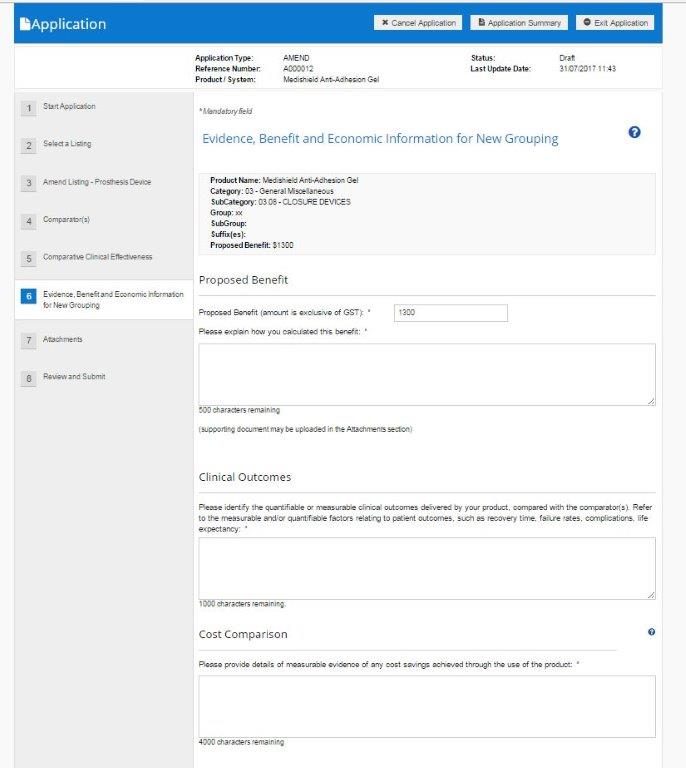
# 1.5 Comparator(s)

**1. Create New Application**

| A comparator is a current product, treatment or therapy that your prosthesis could replace. A comparative product may be similar in form or function to your product. | comparator Details  STEP 1 – Choose the comparator option that applies to your device.   * **Comparator is an existing item on the Prostheses List,** go to STEP 2. * **Comparator is not on the Prostheses List**, go to STEP 8.   STEP 2 – Click Add Comparator.  *You must list at least one comparator in your application. Choosing the right comparator(s) is important as it allows clinicians to better understand and assess your product by comparing it to similar products, treatments and therapies.* |
| --- | --- |
| 1.5 Comparator(s) *continued*  **1. Create New Application** | STEP 3 – Search the Prostheses List by:   * **Keyword Search**   OR   * **Product Grouping** information using the drop down menus   Click Search.  *If you are aware of an appropriate comparator, search by typing in the billing code for that comparator. If you are not aware of a comparator, you may find an appropriate comparator in the same grouping as your prosthesis.*  STEP 4 – Click on the **Billing Code** hyperlink for your chosen comparator in the **Search Results**. |
| 1.5 Comparator(s) *continued*  **1. Create New Application** | STEP 5 – Click Confirm. Your comparator should now be listed on the page.  STEP 6 – Provide a clear explanation on why you have chosen this comparator in the space provided.  *Things you might consider in your explanation include:*   * *The clinical outcome for the product* * *How the product is used* * *How the product is made*   STEP 7 – Add any additional comparators, if needed.  If you have listed more than one comparator for your product, please indicate which is the main comparator by ticking the box.  *The main comparator is the product that your prosthesis would most often replace.* |
| 1.5 Comparator(s) *continued*  **1. Create New Application** | STEP 8 – Enter the **Treatment/ Therapy Name**.  STEP 9 – Enter a **Description** of the treatment or therapy.  STEP 10 – Enter **Benefit/Cost** details.  STEP 11 – Provide a clear explanation on why you have chosen this comparator in the space provided. |

# 1.6 Evidence, Benefit and Economic Information for New Grouping

**1. Create New Application**

You only need to fill out this page if you have proposed a new Group, Subgroup or Suffix in the New Prosthesis Device section (1.4 of this guide). The Evidence, Benefit and Economic Information for New Grouping page will only appear on your application if applicable.

**PROPOSED BENEFIT**

STEP 1 – Enter the **Proposed Benefit** amount for the product.

STEP 2 – Enter an explanation on how you calculated the benefit amount.

*Your explanation should take into consideration:*

* *Clinical outcomes delivered by the product*
* *Cost comparisons or savings achived by using the product*

**CLINICAL OUTCOMES**

STEP 3 – Enter the **Clinical Outcomes** delivered by your product.

*Include information on the differences in clinical outcomes for patients between your prosthesis and any comparators.*

*Factors you may like to consider include:*

* *Recovery times*
* *Failure rates*
* *Complications*
* *Life expectancy*

*The information you provide must be measurable or quantifiable, as well as supported by clinical evidence or data.*

*Please provide evidence to support your claim in the Attachments section (1.10 of this guide).*

| 1.6 Evidence, Benefit and Economic Information for New Grouping *continued* **1. Create New Applicationate New Application** | **COST COMPARISON**  STEP 4 – Enter details of any cost savings achieved by using the product.  *Include information on any cost savings that can be made by using the product instead of the comparator.*  *You may like to consider reductions in:*   * *Theatre time* * *Hospital stay time* * *Post-surgical care costs* * *Reduced revision surgery*   *Any reductions listed must be real (not potential or theoretical), and be supported by clinical evidence or data. For any cost savings listed, please include actual amounts.*  *Please provide evidence to support your claim in the Attachments section (1.10 of this guide).* |
| --- | --- |

# 1.6 Evidence, Benefit and Economic Information for New Grouping *continued*

**1. Create New Application**

|  |  |
| --- | --- |
|  | **PRODUCT UTILISATION**  STEP 5 – Enter into the grey box, the name of any country where your product is sold, and select the correct option from the drop down list.  Enter **Utilisation per year** in the grey box.  Enter **Cost (in local currency)** in the grey box.  Repeat steps for additional countries.  *Please provide actual utilisation and price information for the product in both public and private markets.*  *If the product has been used in the public system in Australia, please include details.*  STEP 6 – Briefly describe the projected utilisation of the product over the first two years of listing on the Prostheses List.  Briefly describe the basis for your projection by providingevidence to support your projected utilisation.  STEP 7 – Click **Yes** or **No** to indicate whether the use of your product would replace another product.  **OTHER INFORMATION**  STEP 8 – Provide any additional information to support the proposed grouping. |

# 1.7 MBS Item(s)

**1. Create New Application**

The Medical Benefits Schedule (MBS) contains a listing of all the Medicare professional services subsidised by the Australian Government.

To be eligible for the Prostheses List, your product must have an MBS listed service for either the implantation or application of the product.

|  |  |
| --- | --- |
|  | **MEDICAL BENEFITS SCHEDULE (MBS) ITEMS(S) AND DESCRIPTORS**  STEP 1 – If you have a current MBS Item number(s) for your product, got to STEP 2.  If you do not have a current MBS Item number(s) for your product, go to STEP 7.  STEP 2 – To add an MBS Item number, click Add MBS Item.  A **Keyword Search** box will appear. |

# 1.7 MBS Item(s) *continued*

**1. Create New Application**

**1. Create New Application**

|  |  |
| --- | --- |
|  | **MEDICAL BENEFITS SCHEDULE (MBS) ITEMS(S) AND DESCRIPTORS**  STEP 3 – Search for an MBS Item by entering either the MBS Item number or MBS Item description.  Click Search.  STEP 4 – Click on the **MBS Item Number** hyperlink for your chosen option. |
| 1.7 MBS Item(s) *continued*  **1. Create New Application** | |
|  | **MEDICAL BENEFITS SCHEDULE (MBS) ITEMS(S) AND DESCRIPTORS**  STEP 5 – Click Confirm. Your MBS Item should now be listed on the page.  Repeat steps to add another MBS Item.  *You can list up to ten MBS Items for your product.*  STEP 6 – Briefly explain why the service(s) apply to your prosthesis device.  STEP 7 – If you have applied for an MBS Item number for your product, but the decision is pending, tick the box.  *The Department will progress your application without an MBS Item number, however the product will not be listed on the Prostheses List until the sponsor provides a valid MBS Item number to the Department*. |

# 1.8 Product Setting and Product Purpose

**1. Create New Application**

|  |  |
| --- | --- |
|  | **PRODUCT SETTING**  STEP 1– Select the option that applies to your product.   * If you choose **(a)** or **(b)**, go to STEP 3 * If you choose **(c)**, go to STEP 2   *To be eligible for the Prostheses List, your product must be provided as part of treatment in a hospital or hospital substitute treatment.*  STEP 2 – For option **(c)**, provide details on where the product is provided if outside of a hospital setting.  *If the product is used for treatment outside of a hospital setting, it may not be eligible for listing on the Prostheses List.* |

# 1.8 Product Setting and Product Purpose *continued*

**1. Create New Application**

|  |  |
| --- | --- |
|  | **PRODUCT PURPOSE**  STEP 3 – Select the option that that best describes the purpose of the product.   * If you choose **(a)**, go to STEP 4 * If you choose **(b)**, go to STEP 5 * If you choose **(c)**, go to STEP 6   STEP 4 – For option **(a)**, briefly describe what the product does, to support the assessment of the product.  STEP 5 – For option **(b)**, enter the name of the single use aid that works with your product.  Briefly describe what the product does, to support the assessment of the product. |
| 1.8 Product Setting and Product Purpose *continued*  **1. Create New Application** | |
|  | **PRODUCT PURPOSE**  STEP 6 – For option **(c)**, enter the name of the surgically implanted product that works with your product.  Briefly describe what the product does, to support the assessment of the product. |

# 1.9 Comparative Clinical Effectiveness

**1. Create New Application**

|  |  |
| --- | --- |
|  | **OVERSEAS STATUS**  STEP 1 – Select the appropriate option for the product.   * If you choose **Yes**, got to STEP 2 * If you chose **No**, or **Unknown/ Not available**, go to STEP 3   *This information allows clinicians to determine if the product has undergone any clinical assessments in other countries.*  STEP 2 – For option **Yes**, provide information about the approvals.  *You may like to provide:*   * *Information on which countries have given approval for the product* * *Approval certificates (attach certificates in the Attachments section)* * *Any other names the product is sold under*   STEP 3 – Select the appropriate option for the product.  If you choose **Yes**, got to STEP 4  If you chose **No**, go to STEP 5  *This information allows clinicians to determine if the product has undergone any clinical assessments in other countries.*  STEP 4 – For option **Yes**, provide the name(s), the product of system is being sold under in other countries. |

# 1.9 Comparative Clinical Effectiveness *continued*

**1. Create New Application**

|  |  |
| --- | --- |
|  | **COMPARATIVE CLINICAL EFFECTIVENESS**  STEP 5 – Provide details of **Comparative Clinical Effectiveness** for your product. |

# 1.10 Attachments

**1. Create New Application**

The documentation you provide in the Attachments section is used by clinicians to assess your application.

|  |  |
| --- | --- |
|  | **ATTACHMENTS**  STEP 1 – To add an attachment to your application, click Add.  *Only upload documentation:*   * *In PDF format* * *In English* * *Specific to the prosthesis*   *Do NOT upload:*   * *Marketing material for the product*   *One specific study focussing on the prosthesis is better than many studies that do not directly relate to the prosthesis.*  *Please number the attachments in the order you would like them to be viewed.* |

# 1.10 Attachments *continued*

**1. Create New Application**

|  |  |
| --- | --- |
|  | **ATTACHMENTS**  STEP 2 – To add an attachment to your application:   * Click **+ Choose File(s)** to browse your device and insert a file   OR   * Drag and drop your file into the white panel.   The file will now be listed on the **Attachments** screen.  STEP 3 – Add additional attachments as needed.  STEP 4 – Use the drop down menu under **Type** to select the type of document you have uploaded.  STEP 5 – Enter a brief description for each document you have uploaded. |

# 1.11 Review and Submit

**1. Create New Application**

Review all sections of your application to ensure the information you provided is correct.

|  |  |
| --- | --- |
|  | **REVIEW**  STEP 1 – Review all sections of your application to ensure the information you provided is correct.  If you find an error in your application, click **Edit**, at the top right of the section. This will take you back to the relevant page where you can make any edits required.  *Your prosthesis device may have to be clinically reassessed if you do not provide the correct information. This may also cause significant delays in listing the item on the Prostheses List.*  **SUBMIT**  STEP 2 – Tick the box if you agree to the declaration.  STEP 3 – Click Save to save the information provided in your  application or click Submit to submit your application. |

# 1.12 Application Summary

**1. Create New Application**

After you submit your application, you will be directed to the Application Summary for your application.

|  |  |
| --- | --- |
|  | **APPLICATION SUMMARY**  Click Print as RTF, to download your Application Summary in a Word document.  Click Print as PDF, to download your Application Summary in a PDF document.  **ATTACHMENTS**  Click the C:\Users\hayley.cosgrove\AppData\Local\Microsoft\Windows\INetCache\Content.Word\Eye Icon (002).jpgicon to download an attachment from your application. |

# 1.12 Application Summary *continued*

**1. Create New Application**

|  |  |
| --- | --- |
|  | **MANAGE APPLICATION ACCESS**  You can manage access to an application so only the users you authorise will be able to see the application listed on the PLMS.   * **Open to All** means any users in your organisation can view your application. Open to All is the default setting. * **Allow** **Access to** allows you to choose which users in your organisation can view your application. * **Deny Access to** allows you to choose which users in your organisation cannot view your application.   To manage user access to your application:   1. Click either **Allow Access to** or **Deny Access to** 2. To manage users:    * Move all users between the **All** box and the **Selected** by clicking >> or <<   OR   * Move a single user between the **All** box and the **Selected** box by clicking on the user name(s) and clicking> or <  1. Click Save after moving your chosen user(s) to the **Selected** box. |

# 2. Expand a Listing

**2. Expand a Listing**

When you Expand a Listing, you are breaking up a single prostheses listing (covering various prostheses) into multiple new billing codes.

The Department will remove the current billing code for the prosthesis, and replace it with new billing codes for the expanded listings.

You may choose to Expand a Listing if:

* Products within the current listing need to be listed in different groupings
* You wish to charge separately for different parts of the current listing

There is no cost to Expand a Listing.

The steps to Expand a Listing are:

| **Expand a Listing** |
| --- |
| * 1. PLMS Home   2. Start Application   3. Expand a Prostheses Listing   4. New Prosthesis Device   5. Comparator(s)   6. Evidence, Benefit and Economic Information for New Grouping\*   7. Comparative Clinical Effectiveness   8. Attachments   9. Review and Submit |

\* You only need to complete this application step if applicable

# 2.1 PLMS Home

**2. Expand a Listing**

|  | STEP 1 – Click Create Application on the left of the screen. |
| --- | --- |

# 2.2 Start Application

**2. Expand a Listing**

On the Start Application page you have the option to create, expand, compress, amend, duplicate, transfer or delete a listing from the Prostheses List.

|  |  |
| --- | --- |
|  | APPLICATION TYPE  STEP 1 – Select **Expand Listing** using the drop down menu.  **APPLICATION CONTACTS**  STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information.  You can add a **Secondary Contact** to your application, if needed.  STEP 3 – To create a **New Contact** for the application:   * Tick the **Create New Contact** box * Enter **First Name**, **Last Name**, **Phone Number(s**) and **Email** address for the contact   The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department.. |

# 2.3 Expand a Prostheses Listing

**2. Expand a Listing**

On the Expand a Prostheses Listing page, you must select the prosthesis from the Prostheses List you want to expand into multiple billing codes.

|  |  |
| --- | --- |
|  | **SELECT A LISTING**  STEP 1 – Click Select a Listing to select a prosthesis from the Prostheses List. |

# 2.3 Expand a Prostheses Listing *continued*

**2. Expand a Listing**

|  |  |
| --- | --- |
|  | STEP 2 – Search the Prostheses List by:   * **Keyword Search**   OR   * **Product Grouping** information using the drop down menus   Click Search.  STEP 3 – Click on the **Billing Code** hyperlink for your chosen product. |

# 2.3 Expand a Prostheses Listing *continued*

**2. Expand a Listing**

|  |  |
| --- | --- |
|  | STEP 4 – Click Confirm. Boxes under **Selected Listing** should now be prefilled with information on the chosen prosthesis. |

# 2.3 Expand a Prostheses Listing *continued*

**2. Expand a Listing**

|  | **REASON FOR EXPANSION**  STEP 5 – Use the drop down menu to choose the reason for expanding the prostheses listing.  If the reason is different to what is listed, please explain in the space available. |
| --- | --- |

# 2.3 Expand a Prostheses Listing *continued*

**2. Expand a Listing**

|  | **RESULTANT (NEW) PROSTHESES LISTINGS**  STEP 6 – Click Add.  When you Expand a Listing, you will need to complete the following sections for each new/ expanded component one product at a time:   * **New Prosthesis Device**(2.4 of this guide) * **Comparator(s***)* (2.5 of this guide) * **Benefit and Economic Information for New Grouping**(if applicable) (2.6 of this guide) * **Comparative Clinical Effectiveness**(2.7 of this guide)   When you finish adding a component, it will be listed under the **Resultant (new) Prostheses Listings** list.  *Each expanded system component included in your application will receive a unique billing code.*  STEP 8– Add any additional components.  STEP 8– After adding all the expanded components, click Next. |
| --- | --- |

# 2.4 New Prosthesis Device

**2. Expand a Listing**

You will need to fill out the New Prosthesis Device section for each new prosthesis device resulting from the expanded listing.

|  | PRoduct Details  STEP 1 – Enter the **Product Name**.  *The product name is the name the prosthesis is sold under in Australia.*  The information you provide for **Product Name** will be available on the Prostheses List should your application be successful.  STEP 2 – Enter a **Description** of the product.  *Describe the prosthesis in one sentence.*  The information you provide for **Description** will be available on the Prostheses List should your application be successful.  STEP 3 – Enter the **Size** of the product.  *Accurately describe the dimensions of the prosthesis or system in one sentence.*  The information you provide for **Size** will be available on the Prostheses List should your application be successful.  STEP 4 – Enter the **Catalogue Number(s).**  *List the catalogue number(s) under which the product is sold in Australia.* |
| --- | --- |

# 2.4 New Prosthesis Device *continued*

**2. Expand a Listing**

|  |  |
| --- | --- |
|  | artg id number  STEP 5 – If you have a current ARTGentry(ARTG ID Number)for the product, enter the number into the grey box, and select the correct option from the drop down list.  Once selected, the rest of the table should populate with information.  *You will need to provide a new ARTG entry for each new prosthesis device resulting from the expanded listing.*  *An ARTG entry is a number given to products entered and current on the Australian Register of Therapeutic Goods (ARTG).*  *You can find your ARTG entry on the Therapeutic Goods Administration Certificate of Inclusion on the Register.*  STEP 6 – If you have applied to include the product on the ARTG, but the decision is pending, tick the box.  *Only products entered on the ARTG can be listed on the Prostheses List.*  *The Department will progress your Prostheses List application without an ARTG entry, however the product will not be listed on the Prostheses List until the sponsor provides the ARTG entry to the Department.* |

# 2.4 New Prosthesis Device *continued*

**2. Expand a Listing**

View the [grouping schemes](http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslistforms) for each category of product, including Suffix definitions and benefits.

|  |  |
| --- | --- |
|  | Grouping  STEP 7 – Select a **Category** from the drop down menu.  *If the product fits into more than one category, list the category that will represent the greatest use of the product.*  STEP 8 – Select a **Subcategory** from the drop down menu.  STEP 9 – Select a **Group** from the drop down menu.  To add a new Group, click Add, enter the new Group name in the space provided, and click Save.    STEP 10 – Select a **Subgroup** from the drop down menu, if needed.  To add a new Subgroup, click Add, enter the new Subgroup name in the space provided, and click Save.  STEP 11 – Select a **Suffix** from the drop down menu, if needed.  To add a new Suffix, click Add, enter the new Suffix name in the space provided, and click Save.  If you add a new Group, Subgroup or Suffix, you will have to fill out the Evidence, Benefit and Economic Information for New Grouping section (2.6 of this guide). If you suggest a new Group, Subgroup or Suffix, the Department will review your evidence and either accept or decline your suggestion. |

# 2.5 Comparator(s)

**2. Expand a Listing**

A comparator is a current product, treatment or therapy that your prosthesis could replace. A comparative product may be similar in form or function to your product. You will need to fill out the Comparator(s) section for each new prosthesis device resulting from the expanded listing.

|  |  |
| --- | --- |
|  | comparator Details  STEP 1 – Choose the comparator option that applies to your device.   * **Comparator is an existing item on the Prostheses List**, go to STEP 2. * **Comparator is not on the Prostheses List**, go to STEP 8.   STEP 2 – Click Add Comparator.  *You must list at least one comparator in your application. Choosing the right comparator(s) is important as it allows clinicians to better understand and assess your product by comparing it to similar products, treatments and therapies.* |

# 2.5 Comparator(s) *continued*

**2. Expand a Listing**

|  |  |
| --- | --- |
|  | STEP 3 – Search the Prostheses List by:   * **Keyword Search**   OR   * **Product Grouping** information using the drop down menus   Click Search.  *If you are aware of an appropriate comparator, search by typing in the billing code for that comparator. If you are not aware of a comparator, you may find an appropriate comparator in the same grouping as your prosthesis.*  STEP 4 – Click on the **Billing Code** hyperlink for your chosen comparator in the **Search Results**. |

# 2.5 Comparator(s) *continued*

**2. Expand a Listing**

|  |  |
| --- | --- |
|  | STEP 5 – Click Confirm. Your comparator should now be listed on the page.  STEP 6 – Provide a clear explanation on why you have chosen this comparator in the space provided.  *Things you might consider in your explanation include:*   * *The clinical outcome for the product* * *How the product is used* * *How the product is made*   STEP 7 – Add any additional comparators, if needed.  If you have listed more than one comparator for your product, please indicate which is the main comparator by ticking the box.  *The main comparator is the product that your prosthesis would most often replace.* |

# 2.5 Comparator(s) *continued*

**2. Expand a Listing**

|  |  |
| --- | --- |
|  | STEP 8 – Enter the **Treatment/ Therapy Name**.  STEP 9 – Enter a **Description** of the Treatment/ Therapy.  STEP 10 – Enter **Benefit/Cost** details.  STEP 11 – Provide a clear explanation on why you have chosen this comparator in the space provided. |

# 2.6 Evidence, Benefit and Economic Information for New Grouping

**2. Expand a Listing**

You only need to fill out this section if you have proposed a new Group, Subgroup or Suffix in the New Prosthesis Device section (2.4 of this guide). The Evidence, Benefit and Economic Information for New Grouping page will only appear on your application if applicable.

|  |  |
| --- | --- |
|  | **PROPOSED BENEFIT**  STEP 1 – Enter the **Proposed Benefit** amount for the product.  STEP 2 – Enter an explanation on how you calculated the benefit amount.  *Your explanation should take into consideration:*   * *Clinical outcomes delivered by the product* * *Cost comparisons or savings achived by using the product*   **CLINICAL OUTCOMES**  STEP 3 – Enter the **Clinical Outcomes** delivered by your product.  *Include information on the differences in clinical outcomes for patients between your prosthesis and any comparators.*  *Hint: Factors you may like to consider include:*   * *Recovery times* * *Failure rates* * *Complications* * *Life expectancy*   *The information you provide must be measurable or quantifiable, as well as supported by clinical evidence or data.*  *Please provide evidence to support your claim in the Attachments section (2.8 of this guide).* |

# 2.6 Evidence, Benefit and Economic Information for New Grouping *continued*

**2. Expand a Listing**

|  |  |
| --- | --- |
|  | **COST COMPARISON**  STEP 4 – Enter details of any cost savings achieved by using the product.  *Include information on any cost savings that can be made by using the product instead of the comparator.*  *You may like to consider reductions in:*   * *Theatre time* * *Hospital stay time* * *Post-surgical care costs* * *Reduced revision surgery*   *Any reductions listed must be real (not potential or theoretical), and be supported by clinical evidence or data. For any cost savings listed, please include actual amounts.*  *Please provide evidence to support your claim in the Attachments section (2.8 of this guide).* |

# 2.6 Evidence, Benefit and Economic Information for New Grouping *continued*

**2. Expand a Listing**

|  |  |
| --- | --- |
|  | **PRODUCT UTILISATION**  STEP 5 – Enter into the grey box, the name of any country where your product is sold, and select the correct option from the drop down list.  Enter **Utilisation per year** in the grey box.  Enter **Cost (in local currency)** in the grey box.  Repeat for additional countries.  *Please provide actual utilisation and price information for the product in both public and private markets.*  *If the product has been used in the public system in Australia, please include details.*  STEP 6 – Briefly describe the projected utilisation of the product over the first two years of listing on the Prostheses List.  Briefly describe the basis for your projection by providingevidence to support your projected utilisation.  STEP 7 – Click **Yes** or **No** to indicate whether the use of your product would replace another product.  **OTHER INFORMATION**  STEP 8 – Provide any additional information to support the proposed grouping. |

# 2.7 Comparative Clinical Effectiveness

**2. Expand a Listing**

You will need to fill out the Comparative Clinical Effectiveness section for each new prosthesis device resulting from the expanded listing.

|  |  |
| --- | --- |
|  | **COMPARATIVE CLINICAL EFFECTIVENESS**  STEP 1 – Provide details of **Comparative Clinical Effectiveness** for your product.  . |

# 2.8 Attachments

**2. Expand a Listing**

The documentation you provide in this section is used by clinicians to assess your application. You will need to provide separate documentation for each new prosthesis device resulting from the expanded listing.

|  |  |
| --- | --- |
|  | **ATTACHMENTS**  STEP 1 – To add an attachment to your application, click Add.  *Only upload documentation:*   * *In PDF format* * *In English* * *Specific to the prosthesis*   *Please label each individual component on the product image that is being expanded into new billing codes.*  *Do NOT upload:*   * *Marketing material for the product*   *Please number the attachments in the order you would like them to be viewed.* |

# 2.8 Attachments *continued*

**2. Expand a Listing**

|  |  |
| --- | --- |
|  | **ATTACHMENTS**  STEP 2 – To add an attachment to your application:   * Click **+ Choose File(s)** to browse your device and insert a file   OR   * Drag and drop your file into the white panel.   The file will now be listed on the **Attachments** screen.  STEP 3 – Add additional attachments as needed.  STEP 4 – Use the drop down menu under **Type** to select the type of document you have uploaded.  STEP 5 – Enter a brief description for each document you have uploaded. |

# 2.9 Review and Submit

**2. Expand a Listing**

Review all sections of your application to ensure the information you provided is correct.

|  |  |
| --- | --- |
|  | **REVIEW**  STEP 1 – Review all sections of your application to ensure the information you provided is correct.  If you find an error in your application, click **Edit**, at the top right of the section. This will take you back to the relevant page where you can make any edits required.  **SUBMIT**  STEP 2 – Tick the box if you agree to the declaration.  STEP 3 – Click Save to save the information provided in your  application or click Submit to submit your application. |

# 3. Compress a Listing

**3. Compress a Listing**

When you Compress a Listing, you are bringing together multiple prostheses on the Prostheses List to sit under a single billing code.

The Department will remove the current billing codes for the prostheses, and replace it with a single new billing code for the compressed listing.

You may choose to Compress a Listing if:

* Related products listed separately on the Prostheses List can now be grouped together e.g. the products are only available in a product system. This may be beneficial as it can reduce your future listing fees.

There is no cost to Compress a Listing.

The steps to Compress a Listing are:

| **Compress a Listing** |
| --- |
| * 1. PLMS Home   2. Start Application   3. Compressed Listings Summary   4. New Prosthesis Device   5. Comparator(s)   6. Evidence, Benefit and Economic Information for New Grouping\*   7. Comparative Clinical Effectiveness   8. Attachments   9. Review and Submit |

\* You only need to complete this application step if applicable

# 3.1 PLMS Home

**3. Compress a Listing**

|  | STEP 1 – Click Create Application on the left of the screen. |
| --- | --- |

# 3.2 Start Application

**3. Compress a Listing**

On the Start Application page you have the option to create, expand, compress, amend, duplicate, transfer or delete a listing from the Prostheses List.

|  |  |
| --- | --- |
|  | APPLICATION TYPE  STEP 1 – Select **Compress a Listing** using the drop down menu.  **APPLICATION CONTACTS**  STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information.  You can add a **Secondary Contact** to your application, if needed.  STEP 3 – To create a **New Contact** for the application:   * Tick the **Create New Contact** box * Enter **First Name**, **Last Name**, **Phone Number(s**) and **Email** address for the contact   The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department. |

# 3.3 Compressed Listings Summary

**3. Compress a Listing**

On the Compressed Listings Summary page, you need to include all the prostheses, currently listed on the Prostheses List, that you want to compress into one billing code.

|  | **SELECT PROSTHESES LISTINGS TO COMPRESS**  STEP 1 – Click Select a Listing to add a prosthesis from the Prostheses List. |
| --- | --- |

# 3.3 Compressed Listings Summary *continued*

**3. Compress a Listing**

|  |  |
| --- | --- |
|  | STEP 2 – Search the Prostheses List by:   * **Keyword Search**   OR   * **Product Grouping** information using the drop down menus   Click Search.  STEP 3 – Click on the **Billing Code** hyperlink for your chosen product. |

# 3.3 Compressed Listings Summary *continued*

**3. Compress a Listing**

|  |  |
| --- | --- |
|  | STEP 4 – Click Confirm. Your product should now be listed on the page under **Select Prostheses Listings to Compress**.  Add additional products to the list, as needed. |

# 3.3 Compressed Listings Summary *continued*

**3. Compress a Listing**

|  | **REASON FOR COMPRESSION**  STEP 5 – Use the drop down menu to choose the reason for compressing the prostheses listings.  If the reason is different to what is listed, please explain in the space available. |
| --- | --- |

# 3.4 New Prosthesis Device

**3. Compress a Listing**

On the New Prosthesis Device page, provide details for the new prosthesis device resulting from the compressed listings.

|  |  |
| --- | --- |
|  | PRoduct Details  STEP 1 – Enter the **Product Name**.  *The product name is the name the prosthesis is sold under in Australia.*  The information you provide for **Product Name** will be available on the Prostheses List should your application be successful.  STEP 2 – Enter a **Description** of the product.  *Describe the prosthesis in one sentence.*  The information you provide for **Description** will be available on the Prostheses List should your application be successful.  STEP 3 – Enter the **Size** of the product.  *Accurately describe the dimensions of the prosthesis or system in one sentence.*  The information you provide for **Size** will be available on the Prostheses List should your application be successful.  STEP 4 – Enter the **Catalogue Number(s).**  *List the catalogue number(s) under which the product is sold in Australia.* |

# 3.4 New Prosthesis Device *continued*

**3. Compress a Listing**

|  |  |
| --- | --- |
|  | artg id number  STEP 5 – If you have a current ARTG entry (ARTG ID Number)for the product, enter the number into the grey box, and select the correct option from the drop down list.  Once selected, the rest of the table should populate with information.  *You will need to provide a new ARTG entry for the compressed prosthesis device.*  *An ARTG entry is a number given to products entered and current on the Australian Register of Therapeutic Goods (ARTG).*  *You can find your ARTG entry on the Therapeutic Goods Administration Certificate of Inclusion on the Register.*  STEP 6 – If you have applied to include the product on the ARTG, but the decision is pending, tick the box.  *Only products entered on the ARTG can be listed on the Prostheses List.*  *The Department will progress your Prostheses List application without an ARTG entry, however the product will not be listed on the Prostheses List until the sponsor provides the ARTG entry to the Department.* |

# 3.4 New Prosthesis Device *continued*

**3. Compress a Listing**

View the [grouping schemes](http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslistforms) for each category of product, including Suffix definitions and benefits.

|  |  |
| --- | --- |
|  | Grouping  STEP 7 – Select a **Category** from the drop down menu.  *If the product fits into more than one category, list the category that will represent the greatest use of the product.*  STEP 8 – Select a **Subcategory** from the drop down menu.  STEP 9 – Select a **Group** from the drop down menu.  To add a new Group, click Add, enter the new Group name in the space provided, and click Save.    STEP 10 – Select a **Subgrou**p from the drop down menu, if needed.  To add a new Subgroup, click Add, enter the new Subgroup name in the space provided, and click Save.  STEP 11 – Select a **Suffix** from the drop down menu, if needed.  To add a new Suffix, click Add, enter the new Suffix name in the space provided, and click Save.  *If you add a new Group, Subgroup or Suffix, you will have to fill out the Evidence, Benefit and Economic Information for New Grouping section (3.6 of this guide).* *If you suggest a new Group, Subgroup or Suffix, the Department will review your evidence and either accept or decline your suggestion.* |

# 3.5 Comparator(s)

**3. Compress a Listing**

A comparator is a current product, treatment or therapy that your prosthesis could replace. A comparative product may be similar in form or function to your product.

|  |  |
| --- | --- |
|  | comparator Details  STEP 1 – Choose the comparator option that applies to your device.   * **Comparator is an existing item on the Prostheses List**, go to STEP 2. * **Comparator is not on the Prostheses List**, go to STEP 8.   STEP 2 – Click Add Comparator.  *You must list at least one comparator in your application. Choosing the right comparator(s) is important as it allows clinicians to better understand and assess your product by comparing it to similar products, treatments and therapies.* |

# 3.5 Comparator(s) *continued*

**3. Compress a Listing**

|  |  |
| --- | --- |
|  | STEP 3 – Search the Prostheses List by:   * **Keyword Search**   OR   * **Product Grouping** information using the drop down menus   Click Search.  *If you are aware of an appropriate comparator, search by typing in the billing code for that comparator. If you are not aware of a comparator, you may find an appropriate comparator in the same grouping as your prosthesis.*  STEP 4 – Click on the **Billing Code** hyperlink for your chosen comparator in the **Search Results**. |

# 3.5 Comparator(s) *continued*

**3. Compress a Listing**

|  |  |
| --- | --- |
|  | STEP 5 – Click Confirm. Your comparator should now be listed on the page.  STEP 6 – Provide a clear explanation on why you have chosen this comparator in the space provided.  *Things you might consider in your explanation include:*   * *The clinical outcome for the product* * *How the product is used* * *How the product is made*   STEP 7 – Add any additional comparators, if needed.  If you have listed more than one comparator for your product, please indicate which is the main comparator by ticking the box.  *The main comparator is the product that your prosthesis would most often replace.* |

# 3.5 Comparator(s) *continued*

**3. Compress a Listing**

|  |  |
| --- | --- |
|  | STEP 8 – Enter the **Treatment/ Therapy Name**.  STEP 9 – Enter a **Description** of the Treatment/ Therapy.  STEP 10 – Enter **Benefit/Cost** details.  STEP 11 – Provide a clear explanation on why you have chosen this comparator in the space provided. |

# 3.6 Evidence, Benefit and Economic Information for New Grouping

**3. Compress a Listing**

You only need to fill out this page if you have proposed a new Group, Subgroup or Suffix in the New Prosthesis Device section (3.4 of this guide). The Evidence, Benefit and Economic Information for New Grouping page will only appear on your application if applicable.

|  |  |
| --- | --- |
|  | **PROPOSED BENEFIT**  STEP 1 – Enter the **Proposed Benefit** amount for the product.  STEP 2 – Enter an explanation on how you calculated the benefit amount.  *Your explanation should take into consideration:*   * *Clinical outcomes delivered by the product* * *Cost comparisons or savings achived by using the product*   **CLINICAL OUTCOMES**  STEP 3 – Enter the **Clinical Outcomes** delivered by your product.  *Include information on the differences in clinical outcomes for patients between your prosthesis and any comparators.*  *Hint: Factors you may like to consider include:*   * *Recovery times* * *Failure rates* * *Complications* * *Life expectancy*   *The information you provide must be measurable or quantifiable, as well as supported by clinical evidence or data.*  *Please provide evidence to support your claim in the Attachments section (3.8 of this guide).* |

# 3.6 Evidence, Benefit and Economic Information for New Grouping *continued*

**3. Compress a Listing**

|  |  |
| --- | --- |
|  | **COST COMPARISON**  STEP 4 – Enter details of any cost savings achieved by using the product.  *Include information on any cost savings that can be made by using the product instead of the comparator.*  *You may like to consider reductions in:*   * *Theatre time* * *Hospital stay time* * *Post-surgical care costs* * *Reduced revision surgery*   *Any reductions listed must be real (not potential or theoretical), and be supported by clinical evidence or data. For any cost savings listed, please include actual amounts.*  *Please provide evidence to support your claim in the Attachments section (3.8 of this guide).* |

# 3.6 Evidence, Benefit and Economic Information for New Grouping *continued*

**3. Compress a Listing**

|  |  |
| --- | --- |
|  | **PRODUCT UTILISATION**  STEP 5 – Enter into the grey box, the name of any country where your product is sold, and select the correct option from the drop down list.  Enter **Utilisation per year** in the grey box.  Enter **Cost (in local currency)** in the grey box.  Repeat for additional countries.  *Please provide actual utilisation and price information for the product in both public and private markets.*  *If the product has been used in the public system in Australia, please include details.*  STEP 6 – Briefly describe the projected utilisation of the product over the first two years of listing on the Prostheses List.  Briefly describe the basis for your projection by providingevidence to support your projected utilisation.  STEP 7 – Click **Yes** or **No** to indicate whether the use of your product would replace another product.  **OTHER INFORMATION**  STEP 8 – Provide any additional information to support the proposed grouping. |

# 3.7 Comparative Clinical Effectiveness

**3. Compress a Listing**

|  |  |
| --- | --- |
|  | **COMPARATIVE CLINICAL EFFECTIVENESS**  STEP 1 – Provide details of **Comparative Clinical Effectiveness** for your product. |

# 3.8 Attachments

**3. Compress a Listing**

The documentation you provide in this section is used by clinicians to assess your application.

|  |  |
| --- | --- |
|  | **ATTACHMENTS**  STEP 1 – To add an attachment to your application, click Add.  *Only upload documentation:*   * *In PDF format* * *In English* * *Specific to the prosthesis*   *Do NOT upload:*   * *Marketing material for the product*   *Please number the attachments in the order you would like them to be viewed.* |

# 3.8 Attachments *continued*

**3. Compress a Listing**

|  |  |
| --- | --- |
|  | **ATTACHMENTS**  STEP 2 – To add an attachment to your application:   * Click **+ Choose File(s)** to browse your device and insert a file   OR   * Drag and drop your file into the white panel.   The file will now be listed on the **Attachment**s screen.  STEP 3 – Add additional attachments as needed.  STEP 4 – Use the drop down menu under **Type** to select the type of document you have uploaded.  STEP 5 – Enter a brief description for each document you have uploaded. |

# 3.9 Review and Submit

**3. Compress a Listing**

Review all sections of your application to ensure the information you provided is correct.

|  |  |
| --- | --- |
|  | **REVIEW**  STEP 1 – Review all sections of your application to ensure the information you provided is correct.  If you find an error in your application, click **Edit**, at the top right of the section. This will take you back to the relevant page where you can make any edits required.  **SUBMIT**  STEP 2 – Tick the box if you agree to the declaration.  STEP 3 – Click Save to save the information provided in your  application or click Submit to submit your application. |

# 4. Amend a Listing

**4. Amend a Listing**

When you Amend a Listing, you are making a change to the product or benefit details for a prosthesis on the Prostheses List.

The application must undergo clinical reassessment if you make changes to the:

* Product name, size or description
* Grouping or benefit details

There is no cost to Amend a Listing.

The steps to Amend a Listing are:

| **Amend a Listing** |
| --- |
| * 1. PLMS Home   2. Start Application   3. Select a Listing   4. Amend Listing – Prosthesis Device   5. Comparator(s)   6. Evidence, Benefit and Economic Information for New Grouping\*   7. Comparative Clinical Effectiveness   8. Attachments   9. Review and Submit |

\* You only need to complete this application step if applicable

# 4.1 PLMS Home

**4. Amend a Listing**

|  | STEP 1 – Click Create Application on the left of the screen. |
| --- | --- |

# 4.2 Start Application

**4. Amend a Listing**

| On the Start Application page you have the option to create, expand, compress, duplicate, amend, transfer or delete a listing from the Prostheses List. | |
| --- | --- |
|  | APPLICATION TYPE  STEP 1 – Select **Amend a Listing** using the drop down menu.  **APPLICATION CONTACTS**  STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information.  You can add a **Secondary Contact** to your application, if needed.  STEP 3 – To create a **New Contact** for the application:   * Tick the **Create New Contact** box * Enter **First Name**, **Last Name**, **Phone Number(s**) and **Email** address for the contact   The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department. |

# 4.3 Select a Listing

**4. Amend a Listing**

|  |  |
| --- | --- |
|  | **SELECTED LISTING**  STEP 1 – Click the option for**Prosthesis Device***.*  STEP 2 – Click Select a Listing to search for the product on the Prostheses List. |

# 4.3 Select a Listing *continued*

**4. Amend a Listing**

|  |  |
| --- | --- |
|  | STEP 3 – Search the Prostheses List by:   * **Keyword Search**   OR   * **Product Grouping** information using the drop down menus   Click Search.  STEP 4 – Click on the **Billing Code** hyperlink for your chosen product. |

# 4.3 Select a Listing *continued*

**4. Amend a Listing**

|  |  |
| --- | --- |
|  | STEP 5 – Click Confirm. Boxes under **Selected Listing** should now be prefilled with information on the chosen prosthesis. |

# 4.3 Select a Listing *continued*

**4. Amend a Listing**

|  |  |
| --- | --- |
|  | STEP 6 – Use the drop down menu to select a reason for the amendment.  If the reason is different to what is listed, please explain in the space available. |

# 4.4 Amend Listing – Prosthesis Device

**4. Amend a Listing**

On the Amend Listing – Prosthesis Device page, Product Details should be prefilled with information on the prosthesis device application you intend to amend.

|  | PRoduct Details  STEP 1 – Make any required changes to the Product Details section.  The information you provide for the **Product Name**, **Description** and **Size** will be available on the Prostheses List should your application be successful. |
| --- | --- |

# 4.4 Amend Listing – Prosthesis Device *continued*

**4. Amend a Listing**

|  | artg id number  STEP 2 – If you have a current ARTGentry(ARTG ID Number)for the product, enter the number into the grey box, and select the correct option from the drop down list.  Once selected, the rest of the table should populate with information.  *The ARTG entry for the product should be the same as for the original listing.*  *An ARTG entry is a number given to products entered and current on the Australian Register of Therapeutic Goods (ARTG).*  *You can find your ARTG entry on the Therapeutic Goods Administration Certificate of Inclusion on the Register.*  STEP 3 – If you have applied to include the product on the ARTG, but the decision is pending, tick the box.  *Only products entered on the ARTG can be listed on the Prostheses List.*  *The Department will progress your Prostheses List application without an ARTG entry, however the product will not be listed on the Prostheses List until the sponsor provides the ARTG entry to the Department.* |
| --- | --- |

# 4.4 Amend Listing – Prosthesis Device *continued*

**4. Amend a Listing**

View the [grouping schemes](http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslistforms) for each category of product, including Suffix definitions and benefits.

|  |  |
| --- | --- |
|  | Grouping  STEP 4 – Use the drop down menus to make any required changes to the **Grouping** section.   * To add a new **Group**, click Add, enter the new Group name in the space provided, and click Save. * To add a new **Subgroup**, click Add, enter the new Subgroup name in the space provided, and click Save. * To add a new **Suffix**, click Add, enter the new Suffix name in the space provided, and click Save.   If you add a new Group, Subgroup or Suffix, you will have to fill out the Evidence, Benefit and Economic Information for New Grouping section (4.7 of this guide). If you suggest a new Group, Subgroup or Suffix, the Department will review your evidence and either accept or decline your suggestion. |

# 4.5 Comparator(s)

**4. Amend a Listing**

A comparator is a current product, treatment or therapy that your prosthesis could replace. A comparative product may be similar in form or function to your product.

|  |  |
| --- | --- |
|  | comparator Details  STEP 1 – Choose the comparator option that applies to your device.   * **Comparator is an existing item on the Prostheses List**, go to STEP 2. * **Comparator is not on the Prostheses List**, go to STEP 8.   STEP 2 – Click Add Comparator.  *You must list at least one comparator in your application. Choosing the right comparator(s) is important as it allows clinicians to better understand and assess your product by comparing it to similar products, treatments and therapies.* |

# 4.5 Comparator(s) *continued*

**4. Amend a Listing**

|  |  |
| --- | --- |
|  | STEP 3 – Search the Prostheses List by:   * **Keyword Search**   OR   * **Product Grouping** information using the drop down menus   Click Search.  *If you are aware of an appropriate comparator, search by typing in the billing code for that comparator. If you are not aware of a comparator, you may find an appropriate comparator in the same grouping as your prosthesis.*  STEP 4 – Click on the **Billing Code** hyperlink for your chosen comparator in the **Search Results**. |

# 4.5 Comparator(s) *continued*

**4. Amend a Listing**

|  |  |
| --- | --- |
|  | STEP 5 – Click Confirm. Your comparator should now be listed on the page.  STEP 6 – Provide a clear explanation on why you have chosen this comparator in the space provided.  *Things you might consider in your explanation include:*   * *The clinical outcome for the product* * *How the product is used* * *How the product is made*   STEP 7 – Add any additional comparators, if needed.  If you have listed more than one comparator for your product, please indicate which is the main comparator by ticking the box.  *The main comparator is the product that your prosthesis would most often replace.* |

# 4.5 Comparator(s) *continued*

**4. Amend a Listing**

|  | STEP 8 – Enter the **Treatment/ Therapy Name**.  STEP 9 – Enter a **Description** of the Treatment/ Therapy.  STEP 10 – Enter **Benefit/Cost** details.  STEP 11 – Provide a clear explanation on why you have chosen this comparator in the space provided. |
| --- | --- |

# 4.6 Comparative Clinical Effectiveness

**4. Amend a Listing**

|  |  |
| --- | --- |
|  | **COMPARATIVE CLINICAL EFFECTIVENESS**  STEP 1 – Provide details of **Comparative Clinical Effectiveness** for your product. |

# 4.7 Evidence, Benefit and Economic Information for New Grouping

**4. Amend a Listing**

You only need to fill out this page if you have proposed a new Group, Subgroup or Suffix in the New Prosthesis Device section (4.4 of this guide). The Evidence, Benefit and Economic Information for New Grouping page will only appear on your application if applicable.

|  |  |
| --- | --- |
|  | **PROPOSED BENEFIT**  STEP 1 – Enter the **Proposed Benefit** amount for the product.  STEP 2 – Enter an explanation on how you calculated the benefit amount.  *Your explanation should take into consideration:*   * *Clinical outcomes delivered by the product* * *Cost comparisons or savings achived by using the product*   **CLINICAL OUTCOMES**  STEP 3 – Enter the **Clinical Outcomes** delivered by your product.  *Include information on the differences in clinical outcomes for patients between your prosthesis and any comparators.*  *Hint: Factors you may like to consider include:*   * *Recovery times* * *Failure rates* * *Complications* * *Life expectancy*   *The information you provide must be measurable or quantifiable, as well as supported by clinical evidence or data.*  *Please provide evidence to support your claim in the Attachments section (4.8 of this guide).* |

# 4.7 Evidence, Benefit and Economic Information for New Grouping *continued*

**4. Amend a Listing**

|  |  |
| --- | --- |
|  | **COST COMPARISON**  STEP 4 – Enter details of any cost savings achieved by using the product.  *Include information on any cost savings that can be made by using the product instead of the comparator.*  *You may like to consider reductions in:*   * *Theatre time* * *Hospital stay time* * *Post-surgical care costs* * *Reduced revision surgery*   *Any reductions listed must be real (not potential or theoretical), and be supported by clinical evidence or data. For any cost savings listed, please include actual amounts.*  *Please provide evidence to support your claim in the Attachments section (4.8 of this guide).* |

# 4.7 Evidence, Benefit and Economic Information for New Grouping *continued*

**4. Amend a Listing**

|  | **PRODUCT UTILISATION**  STEP 5 – Enter into the grey box, the name of any country where your product is sold, and select the correct option from the drop down list.  Enter **Utilisation per year** in the grey box.  Enter **Cost (in local currency)** in the grey box.  Repeat for additional countries.  *Please provide actual utilisation and price information for the product in both public and private markets.*  *If the product has been used in the public system in Australia, please include details.*  STEP 6 – Briefly describe the projected utilisation of the product over the first two years of listing on the Prostheses List.  Briefly describe the basis for your projection by providingevidence to support your projected utilisation.  STEP 7 – Click **Yes** or **No** to indicate whether the use of your product would replace another product.  **OTHER INFORMATION**  STEP 8 – Provide any additional information to support the proposed grouping. |
| --- | --- |

# 4.8 Attachments

**4. Amend a Listing**

The documentation you provide in this section is used by clinicians to assess your application.

|  |  |
| --- | --- |
|  | **ATTACHMENTS**  STEP 1 – To add an attachment to your application, click Add.  *In your supporting documentation, please attach:*   * *A before and after image of the prosthesis* * *An explanation of what is different and why*   *Only upload documentation:*   * *In PDF format* * *In English* * *Specific to the prosthesis*   *Do NOT upload:*   * *Marketing material for the product*   *Please number the attachments in the order you would like them to be viewed.* |

# 4.8 Attachments *continued*

**4. Amend a Listing**

The documentation you provide in this section is used by clinicians to assess your application.

|  |  |
| --- | --- |
|  | **ATTACHMENTS**  STEP 2 – To add an attachment to your application:   * Click **+ Choose File(s)** to browse your device and insert a file   OR   * Drag and drop your file into the white panel.   The file will now be listed on the **Attachments** screen.  STEP 3 – Add additional attachments as needed.  STEP 4 – Use the drop down menu under **Type** to select the type of document you have uploaded.  STEP 5 – Enter a brief description for each document you have uploaded. |

# 4.9 Review and Submit

**4. Amend a Listing**

Review all sections of your application to ensure the information you provided is correct.

|  |  |
| --- | --- |
|  | **REVIEW**  STEP 1 – Review all sections of your application to ensure the information you provided is correct.  If you find an error in your application, click **Edit**, at the top right of the section. This will take you back to the relevant page where you can make any edits required.  **SUBMIT**  STEP 2 – Tick the box if you agree to the declaration.  STEP 3 – Click Save to save the information provided in your  application or click Submit to submit your application. |

# 5. Duplicate a Listing

**5. Duplicate a Listing**

When you Duplicate a Listing, you are making a copy of a current prostheses listing held by another sponsor.

When you Duplicate a Listing:

* The original billing code for the prosthesis will remain on the Prostheses List, and you will receive a new billing code for the duplicated product
* The product will not need to be clinically reassessed

There is no cost to Duplicate a Listing.

The steps to Duplicate a Listing are:

| **Duplicate a Listing** |
| --- |
| * 1. PLMS Home   2. Start Application   3. Select a Duplicate Listing   4. Duplicate a Prostheses Listing   5. Attachments   6. Review and Submit |

# 5.1 PLMS Home

**5. Duplicate a Listing**

|  | STEP 1 – Click Create Application on the left of the screen. |
| --- | --- |

# 5.2 Start Application

**5. Duplicate a Listing**

On the Start Application page you have the option to create, expand, compress, duplicate, amend, transfer or delete a listing from the Prostheses List.

|  |  |
| --- | --- |
|  | APPLICATION TYPE  STEP 1 – Select **Duplicate a Listing** using the drop down menu.  **APPLICATION CONTACTS**  STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information.  You can add a **Secondary Contact** to your application, if needed.  STEP 3 – To create a **New Contact** for the application:   * Tick the **Create New Contact** box * Enter **First Name**, **Last Name**, **Phone Number(s**) and **Email** address for the contact   The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department. |

# 5.3 Select a Duplicate Listing

**5. Duplicate a Listing**

On the Select a Duplicate Listing page, select the prosthesis device from the Prostheses List you want to duplicate.

|  |  |
| --- | --- |
|  | **SELECTED LISTING**  STEP 1 – Click Select a Listing to search for the product on the Prostheses List. |

# 5.3 Select a Duplicate Listing *continued*

|  | STEP 3 – Search the Prostheses List by:   * **Keyword Search**   OR   * **Product Grouping** information using the drop down menus   Click Search.  STEP 4 – Click on **the Billing Code** hyperlink for your chosen product. |
| --- | --- |

# 5.3 Select a Duplicate Listing *continued*

**5. Duplicate a Listing**

|  |  |
| --- | --- |
|  | STEP 5 – Click Confirm. Boxes under **Selected Listing** should now be prefilled with information on the chosen prosthesis. |

# 5.4 Duplicate a Prostheses Listing

**5. Duplicate a Listing**

On the Duplicate a Prostheses Listing page, the Product Details will be prefilled with information.

|  |  |
| --- | --- |
|  | PRoduct Details  STEP 1 – Enter the **Catalogue Number(s).**  *List the catalogue number(s) under which the product is sold in Australia.* |

# 5.4 Duplicate a Prostheses Listing *continued*

**5. Duplicate a Listing**

|  |  |
| --- | --- |
|  | artg id number(s)  STEP 2 – If you have a current ARTGentry(ARTG ID Number)for the product, enter the number into the grey box, and select the correct option from the drop down list.  Once selected, the rest of the table should populate with information.  *You will need to provide a new ARTG entry for the duplicated prosthesis device.*  *An ARTG entry is a number given to products entered and current on the Australian Register of Therapeutic Goods (ARTG).*  *You can find your ARTG entry on the Therapeutic Goods Administration Certificate of Inclusion on the Register.*  STEP 3 – If you have applied to include the product on the ARTG, but the decision is pending, tick the box.  *Only products entered on the ARTG can be listed on the Prostheses List.*  *The Department will progress your Prostheses List application without an ARTG entry, however the product will not be listed on the Prostheses List until the sponsor provides the ARTG entry to the Department.* |

# 5.5 Attachments

**5. Duplicate a Listing**

The documentation you provide in this section is used by clinicians to assess your application.

|  |  |
| --- | --- |
|  | **ATTACHMENTS**  STEP 1 – To add an attachment to your application, click Add.  *In your supporting documentation, please attach:*   * *A letter of authority from the original sponsor giving approval for the duplication*   *Only upload documentation:*   * *In PDF format* * *In English* * *Specific to the prosthesis*   *Do NOT upload:*   * *Marketing material for the product*   *Please number the attachments in the order you would like them to be viewed.* |

# 5.5 Attachments *continued*

**5. Duplicate a Listing**

|  |  |
| --- | --- |
|  | **ATTACHMENTS**  STEP 2 – To add an attachment to your application:   * Click **+ Choose File(s)** to browse your device and insert a file   OR   * Drag and drop your file into the white panel.   The file will now be listed on the **Attachments** screen.  STEP 3 – Add additional attachments as needed.  STEP 4 – Use the drop down menu under **Type** to select the type of document you have uploaded.  STEP 5 – Enter a brief description for each document you have uploaded. |

# 5.6 Review and Submit

**5. Duplicate a Listing**

Review all sections of your application to ensure the information you provided is correct.

|  |  |
| --- | --- |
|  | **REVIEW**  STEP 1 – Review all sections of your application to ensure the information you provided is correct.  If you find an error in your application, click **Edit**, at the top right of the section. This will take you back to the relevant page where you can make any edits required.  **SUBMIT**  STEP 2 – Tick the box if you agree to the declaration.  STEP 3 – Click Save to save the information provided in your  application or click Submit to submit your application. |

# 6. Transfer a Listing

**6. Transfer a Listing**

When you Transfer a Listing, you are transferring a current prostheses listing to your organisation from another sponsor.

The receiving sponsor is responsible for submitting the application to transfer a listing.

There is no cost to Transfer a Listing.

The steps to Transfer a Listing are:

| **Transfer a Listing** |
| --- |
| * 1. PLMS Home   2. Start Application   3. Transfer a Prostheses Listing   4. Attachments   5. Review and Submit |

# 6.1 PLMS Home

**6. Transfer a Listing**

|  | STEP 1 – Click Create Application on the left of the screen. |
| --- | --- |

# 6.2 Start Application

**6. Transfer a Listing**

On the Start Application page you have the option to create, expand, compress, duplicate, amend, transfer or delete a listing from the Prostheses List.

|  |  |
| --- | --- |
|  | APPLICATION TYPE  STEP 1 – Select **Transfer a Listing** using the drop down menu.  **APPLICATION CONTACTS**  STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information.  You can add a **Secondary Contact** to your application, if needed.  STEP 3 – To create a **New Contact** for the application:   * Tick the **Create New Contact** box * Enter **First Name**, **Last Name**, **Phone Number(s**) and **Email** address for the contact   The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department. |

# 6.3 Transfer a Prostheses Listing

**6. Transfer a Listing**

On the Transfer a Prostheses Listing page, select the prostheses listing you want to transfer to your organisation.

|  |  |
| --- | --- |
|  | **SELECTED LISTING**  STEP 1 – Click Select a Listing to search for the product on the Prostheses List. |

# 6.3 Transfer a Prostheses Listing *continued*

**6. Transfer a Listing**

|  |  |
| --- | --- |
|  | STEP 2 – Search the Prostheses List by:   * **Keyword Search**   OR   * **Product Grouping** information using the drop down menus   Click Search.  STEP 3 – Click on the **Billing Code** hyperlink for your chosen product. |

# 6.3 Transfer a Prostheses Listing *continued*

**6. Transfer a Listing**

|  |  |
| --- | --- |
|  | STEP 4 – Click Confirm. Boxes under **Selected Listing** should now be prefilled with information on the chosen prosthesis. |

# 6.3 Transfer a Prostheses Listing *continued*

**6. Transfer a Listing**

|  |  |
| --- | --- |
|  | CATALOGUE nUMBER(S)  STEP 5 – Enter the **Catalogue Number(s).**  *List the catalogue number(s) under which the product is sold in Australia.*  artg id number(s)  STEP 6 – If you have a current ARTGentry(ARTG ID Number)for the product, enter the number into the grey box, and select the correct option from the drop down list.  Once selected, the rest of the table should populate with information.  *You will need to provide a new ARTG entry for the prosthesis device when transferring it to your organisation.*  *An ARTG entry is a number given to products entered and current on the Australian Register of Therapeutic Goods (ARTG).*  *You can find your ARTG entry on the Therapeutic Goods Administration Certificate of Inclusion on the Register.*  STEP 7 – If you have applied to include the product on the ARTG, but the decision is pending, tick the box.  *Only products entered on the ARTG can be listed on the Prostheses List.*  *The Department will progress your Prostheses List application without an ARTG entry, however the product will not be listed on the Prostheses List until the sponsor provides the ARTG entry to the Department.* |

# 6.4 Attachments

**6. Transfer a Listing**

The documentation you provide in this section is used by clinicians to assess your application.

|  |  |
| --- | --- |
|  | **ATTACHMENTS**  STEP 1 – To add an attachment to your application, click Add.  *In your supporting documentation, please attach:*   * *A letter or authority from the original sponsor and new sponsor giving approval for the transfer.*   *Only upload documentation:*   * *In PDF format* * *In English* * *Specific to the prosthesis*   *Do NOT upload:*   * *Marketing material for the product*   *Please number the attachments in the order you would like them to be viewed.* |

# 6.4 Attachments *continued*

**6. Transfer a Listing**

|  | **ATTACHMENTS**  STEP 2 – To add an attachment to your application:   * Click **+ Choose File(s)** to browse your device and insert a file   OR   * Drag and drop your file into the white panel.   The file will now be listed on the **Attachments** screen.  STEP 3 – Add additional attachments as needed.  STEP 4 – Use the drop down menu under **Type** to select the type of document you have uploaded.  STEP 5 – Enter a brief description for each document you have uploaded. |
| --- | --- |

# 6.5 Review and Submit

**6. Transfer a Listing**

Review all sections of your application to ensure the information you provided is correct.

|  |  |
| --- | --- |
|  | **REVIEW**  STEP 1 – Review all sections of your application to ensure the information you provided is correct.  If you find an error in your application, click **Edit**, at the top right of the section. This will take you back to the relevant page where you can make any edits required.  **SUBMIT**  STEP 2 – Tick the box if you agree to the declaration.  STEP 3 – Click Save to save the information provided in your  application or click Submit to submit your application. |

# 7. Delete a Listing

When you Delete a Listing, you are removing a product from the Prostheses List.

You may choose to Delete a Listing if:

* Your organisation no longer sells the product, and it is not being transferred to another sponsor
* The product is being replaced by another product
* The product is no longer registered on the ARTG
* The company no longer exists

The listing for the product will be removed on the next version of the Prostheses List.

There is no cost to Delete a Listing deleting a listing.

The steps to Delete a Listing are:

| **Delete a Listing** |
| --- |
| * 1. PLMS Home   2. Start Application   3. Delete a Listing   4. Review and Submit |

# 7.1 PLMS Home

**7. Delete a Listing**

|  | STEP 1 – Click Create Application on the left of the screen. |
| --- | --- |

# 7.2 Start Application

**7. Delete a Listing**

On the Start Application page you have the option to create, expand, compress, duplicate, amend, transfer or delete a listing from the Prostheses List.

|  |  |
| --- | --- |
|  | APPLICATION TYPE  STEP 1 – Select **Delete a Listing** using the drop down menu.  **APPLICATION CONTACTS**  STEP 2 – Select a **Primary Contact** for your application using the drop down menu. This action should prefill contact information.  You can add a **Secondary Contact** to your application, if needed.  STEP 3 – To create a **New Contact** for the application:   * Tick the **Create New Contact** box * Enter **First Name**, **Last Name**, **Phone Number(s**) and **Email** address for the contact   The Department uses the contact information for invoicing and to liaise with the sponsor about the application. Only provide details for a sponsor who is familiar with the application and can answer any further questions from the Department. |

# 7.3 Delete a Listing

**7. Delete a Listing**

On the Delete a Listing page, select the prosthesis device from the Prostheses List you wish to delete.

|  |  |
| --- | --- |
|  | **DELETE A LISTING**  STEP 1 – Click the option for**Prosthesis Device***.*  **SELECTED LISTING**  STEP 2 – Click Select a Listing to search for the product on the Prostheses List. |

# 7.3 Delete a Listing *continued*

**7. Delete a Listing**

|  |  |
| --- | --- |
|  | STEP 3 – Search the Prostheses List by:   * **Keyword Search**   OR   * **Product Grouping** information using the drop down menus   Click Search.  STEP 4 – Click on the **Billing Code** hyperlink for your chosen product. |

# 7.3 Delete a Listing *continued*

**7. Delete a Listing**

|  |  |
| --- | --- |
|  | STEP 5 – Click Confirm. Your product should now be listed on the page.  **REASON FOR DELETION**  STEP 6 – Use the drop down menu to select a reason for deleting the product from the Prostheses List. |

# 7.4 Review and Submit

**7. Delete a Listing**

Review all sections of your application to ensure the information you provided is correct.

|  | **REVIEW**  STEP 1 – Review all sections of your application to ensure the information you provided is correct.  If you find an error in your application, click **Edit**, at the top right of the section. This will take you back to the relevant page where you can make any edits required.  **SUBMIT**  STEP 2 – Tick the box if you agree to the declaration.  STEP 3 – Click Save to save the information provided in your  application or click Submit to submit your application. |
| --- | --- |