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|  | TGA use only |  |
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This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <<https://www.tga.gov.au/treatment-information-provided-tga>>.

# Special Access Scheme – Category B (June 2022)

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| Important information**Email completed form to** **SAS@health.gov.au** **(preferred) or fax to 02 6203 1105.****The SAS Category B application form should be completed if guidance for use of an unapproved good will be met and the SAS Category A or SAS Category C pathways are not applicable.** | Privacy informationFor general privacy information, go to <<https://www.tga.gov.au/privacy>>.The TGA is collecting personal information in this form in order to:* Assess the application.
* Contact the health practitioner and discuss the application where necessary.
* The personal information of the health practitioner may be disclosed to State and Territory authorities with responsibility for therapeutic goods or medical practitioner registration.
 |
| **Do not provide the name of the patient. Only provide the patient’s initials and other information as requested on this form.****Please complete the form clearly and in full. Applications cannot be assessed if the form is incomplete or illegible. PLEASE PRINT IN BLOCK LETTERS.** |

Patient details (do not provide the patient’s name – provide at least three patient identifiers)

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| **Patient initials**      | **Gender**Male [ ]  Female [ ]  Intersex/Indeterminate/Unspecified [ ]  | **DOB**      | **MRN** (if applicable)      |
| **Diagnosis(es)**       | **Previous SAS No.** (if applicable)      |
| **Indication**       |
| **Clinical justification for use of product** (e.g. outline of the patient’s symptoms and/or diagnosis, details of relevant past treatments and procedures trialled or considered, reasons why therapeutic goods currently included in the ARTG may not be the most appropriate treatment for the individual patient in the particular circumstance, an appraisal of the expected clinical benefits versus the potential risks – DO NOT LEAVE BLANK)      |

***The Special Access Scheme is available for exceptional circumstances where the prescribing health practitioner has considered appropriate treatment options included in the Australian Register of Therapeutic Goods (ARTG).***

* **I confirm that I have considered approved and available treatments for this patient** [ ]

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| Medicine [ ]  Biological [x]

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| **Trade Name** (if known)BiomeBoost/BIOMICTRA | **Sponsor / Supplier**BiomeBank |
| **Active ingredient(s)**Faecal microbiota |
| **Dosage form** (e.g. tablet)Suspension | **Strength** (e.g., 1 mg/ml)12.5 g human donor faecal microbiota |
| **Route of administration** (e.g., IV)Colonoscopy or Enema | **Dose & frequency** (1 tds)      |
| **Expected duration of treatment**       |

 | Medical device

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| **Trade name**      |
| **Product description** (including variant[[1]](#footnote-1))      |
| **No of units to be supplied**      | **Sponsor / Supplier**      |
| **Expected duration of treatment**      | **Intended date of use**      |

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**Product details (attach efficacy and safety data to support proposed use of the product and details of intended monitoring)**

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| Prescribing health practitioner details

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| **First name**      | **Surname**      |
| **AHPRA ID**      | **Health practitioner**[[2]](#endnote-1) **type**      |
| **Email**      | **Speciality**      |
| **Fax**      | **Phone**      |
| **Principal practice address**      |

 | Submitter details (if different)

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| **Business or practice name**      | **AHPRA ID**      |
| **First name** (as per AHPRA registration)      | **Surname**      |
| **Health practitioner type**      | **Fax**      |
| **Email**      | **Phone**      |
| **Preferred Contact:**[ ]  Prescribing health practitioner[ ]  Submitter | **Preferred contact method:**Email [ ]  Fax [ ]  Phone [ ]  |

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| **Please note that the giving of false or misleading information is an offence under the *Criminal Code Act 1995* and that penalties may be imposed.** |
| **Submitter’s signature** | **Date**      |

**Please send this form to the TGA only**

1. Variant means a medical device the design of which has been varied to accommodate different patient anatomical requirements (for example, relating to the shape, size, length, diameter or gauge of the device) [↑](#footnote-ref-1)
2. [↑](#endnote-ref-1)