



Australian Government

Department of Health

Information for Healthcare Professionals Pharmaceutical Benefits Scheme Listing Changes – Biosimilar INFLIXIMAB

Inflectra® and Renflexis® are biosimilar brands of infliximab and are listed on the Pharmaceutical Benefits Scheme (PBS) together with the reference biological medicine Remicade®.

A number of changes to PBS listings for infliximab have been made recently which support Australian Government initiatives to encourage the use of biosimilar brands of biological medicines. These include the application of biosimilar uptake drivers and certain changes in the availability of substitution between brands of infliximab on the PBS.

On 1 October 2019 the private hospital listings were amended to Authority Required (Streamlined) in the instances where the medicine is already listed with this authority level for public hospitals.

On 1 November 2019 further PBS listing amendments were made. These allow for brand substitution where prescriptions are Authority Required (Written) at the subsequent continuing treatment phase. These changes are indicated **in red**.

A summary of the infliximab PBS listings for each indication is provided in the **tables below**. Refer to the Schedule of Pharmaceutical Benefits, available [online](#), in [PDF](#) and in prescribing software, for initial, first continuing and subsequent continuing treatment phase criteria and eligibility details.

Further information for healthcare professionals regarding the use of PBS authorities and claiming of PBS benefits is available at the [Department of Human Services](#) website.

More Information

The Biosimilars Awareness Initiative webpage on the [Australian Government Department of Health website](#) provides information about biosimilar medicines.

The biosimilars regulation page on the [Therapeutic Goods Administration website](#) explains the process for approval of biosimilar medicines for use in Australia.

The [Pharmaceutical Benefits Advisory Committee recommendation on the infliximab uptake drivers](#) is available on the PBS website.

Further information about the application of biosimilar uptake drivers to infliximab is also available on the [Biosimilars webpage](#) of the PBS website.

TABLES

a = brands may be substituted by the pharmacist within each PBS item listing, in consultation with the patient and provided the prescriber has not written 'brand substitution not permitted' on the prescription.

For Authority Required (Streamlined) listings, prescribers need to request authority approval from the Department of Human Services to prescribe increased quantity and/or repeats in line with the PBS restriction.

As part of the PBS listing changes from 1 October 2019, private hospital prescriptions are now Authority Required (Streamlined) to be equivalent to public hospital authority requirements.

Infliximab PBS Listings Summary for treatment of Severe Chronic Plaque Psoriasis

Form / Strength	Brand / a flag	Treatment Phase	Authority Level/Code	Program / Prescribing setting	PBS Item Code for Claiming
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Initial 1 (Whole body, new patient) Initial 2 (Whole body, change or recommencement after break < 5 years) Initial 3 (Whole body, recommencement after break > 5 years) Initial 1 (Face, hand, foot, new patient)	Written	s100 HSD Public s100 HSD Private	5758C 9617E

Form / Strength	Brand / a flag	Treatment Phase	Authority Level/Code	Program / Prescribing setting	PBS Item Code for Claiming
		<p>Initial 2 (Face, hand, foot,, change or recommencement after break < 5 years)</p> <p>Initial 3 (Face, hand, foot,, recommencement after break > 5 years)</p> <p>First continuing (Whole body or Face, hand, foot)</p> <p>(Note – for initial and continuing treatment, authority approval for sufficient therapy to complete the balance of supply may be requested by telephone)</p>			
Infliximab 100mg injection, 1 vial	<p>Inflectra a</p> <p>Remicade a</p> <p>Renflexis a</p>	Subsequent continuing	Written	<p>s100 HSD Public</p> <p>s100 HSD Private</p>	<p>11606W</p> <p>11590B</p>
Infliximab 100mg injection, 1 vial	<p>Inflectra a</p> <p>Renflexis a</p>	Subsequent continuing	<p>Streamlined - Whole body (8844)</p> <p>Streamlined - Face, hand, foot (8940)</p> <p>Streamlined - Whole body (9602)</p> <p>Streamlined - Face, Hand, foot (9584)</p>	<p>s100 HSD Public</p> <p>s100 HSD Public</p> <p>s100 HSD Private</p> <p>s100 HSD Private</p>	<p>11605T</p> <p>11605T</p> <p>11595G</p> <p>11595G</p>

Infliximab PBS Listings Summary for treatment of Adult Patients with Severe Active Psoriatic Arthritis

Form / Strength	Brand / a flag	Treatment Phase	Authority Level/Code	Program / Prescribing setting	PBS Item Code for Claiming
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Initial 1 (New patient) Initial 2 (Change or recommencement after break < 5 years) Initial 3 (Recommencement after break > 5 years) First continuing (Note – for initial and continuing treatment, authority approval for sufficient therapy to complete the balance of supply may be requested by telephone)	Written	s100 HSD Public s100 HSD Private	5756Y 6496X
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Subsequent continuing	Written	s100 HSD Public s100 HSD Private	11497D 11498E
Infliximab 100mg injection, 1 vial	Inflectra a Renflexis a	Subsequent continuing	Streamlined (9188) Streamlined (9472)	s100 HSD Public s100 HSD Private	11514B 11515C

Infliximab PBS Listings Summary for treatment of Ankylosing Spondylitis

Form / Strength	Brand / a flag	Treatment Phase	Authority Level/Code	Program / Prescribing setting	PBS Item Code for Claiming
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Initial 1 (New patient) Initial 2 (Change or recommencement after break < 5 years) Initial 3 (Recommencement after break > 5 years) First continuing (Note – for initial and continuing treatment, authority approval for sufficient therapy to complete the balance of supply may be requested by telephone)	Written	s100 HSD Public s100 HSD Private	5753T 6448J
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Subsequent continuing	Written	s100 HSD Public s100 HSD Private	11482H 11489Q
Infliximab 100mg injection, 1 vial	Inflectra a Renflexis a	Subsequent continuing	Streamlined (9481) Streamlined (9621)	s100 HSD Public s100 HSD Private	11486M 11488P

Infliximab PBS Listings Summary for treatment of Severe Active Rheumatoid Arthritis

Form / Strength	Brand / a flag	Treatment Phase	Authority Level/Code	Program / Prescribing setting	PBS Item Code for Claiming
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Initial 1 (New patient) Initial 2 (Change or recommencement after break < 24 months) Initial 3 (Recommencement after break > 24 months) First continuing (Note – for initial and continuing treatment, authority approval for sufficient therapy to complete the balance of supply may be requested by telephone)	Written	s100 HSD Public s100 HSD Private	5757B 6397Q
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Subsequent continuing	Written	s100 HSD Public s100 HSD Private	11481G 11487N
Infliximab 100mg injection, 1 vial	Inflectra a Renflexis a	Subsequent continuing	Streamlined (8755) Streamlined (9615)	s100 HSD Public s100 HSD Private	11490R 11483J

Infliximab PBS Listings Summary for treatment of Moderate to Severe Ulcerative Colitis

Form / Strength	Brand / a flag	Treatment Phase	Authority Level/Code	Program / Prescribing setting	PBS Item Code for Claiming
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Initial 1 (New patient) Initial 2 (Change or recommencement after break < 5 years) Initial 3 (Recommencement after break > 5 years) First continuing (Note – authority approval for sufficient therapy to complete the balance of supply may be requested by telephone)	Written	s100 HSD Public s100 HSD Private	10196P 10184B
Infliximab 100mg injection, 1 vial	Remicade a Inflectra a Renflexis a	Continuing	Telephone	s100 HSD Private	11797X
Infliximab 100mg injection, 1 vial	Remicade a Inflectra a Renflexis a	Continuing	Telephone	s100 HSD Public	11459D
Infliximab 100mg injection, 1 vial	Inflectra a Renflexis a	Continuing	Streamlined (9806)	s100 HSD Private	11796W
Infliximab 100mg injection, 1 vial	Inflectra a Renflexis a	Continuing	Streamlined (9785)	s100 HSD Public	11461F

Infliximab PBS Listings Summary for treatment of Paediatric Patients with Refractory Crohn Disease

Form / Strength	Brand / a flag	Treatment Phase	Authority Level/Code	Program / Prescribing setting	PBS Item Code for Claiming
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Initial 1 (New patient) Initial 2 (Change or recommencement after break < 5 years) Initial 3 (Recommencement after break > 5 years) First continuing (Note – authority approval for sufficient therapy to complete the balance of supply for paediatric patients may be requested by telephone)	Written	s100 HSD Public s100 HSD Private	5755X 9612X
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Subsequent continuing	Written	s100 HSD Public s100 HSD Private	11448M 11445J
Infliximab 100mg injection, 1 vial	Inflectra a Renflexis a	Subsequent continuing	Streamlined (9668)	s100 HSD Public	11449N
Infliximab 100mg injection, 1 vial	Inflectra a Renflexis a	Subsequent continuing	Streamlined (9775)	s100 HSD Private	11450P

Infliximab PBS Listings Summary for Complex Refractory Fistulising Crohn Disease

Form / Strength	Brand / a flag	Treatment Phase	Authority Level/Code	Program / Prescribing setting	PBS Item Code for Claiming
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Initial treatment (new patient or Recommencement after break > 5 years - Initial 1) Change or Recommencement after break < 5 years (Initial 2) First continuing (Note – authority approval for sufficient therapy to complete the balance of supply may be requested by telephone)	Written	s100 HSD Public s100 HSD Private	9654D 9674E
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Subsequent continuing	Written	s100 HSD Public s100 HSD Private	11424G 11412P
Infliximab 100mg injection, 1 vial	Inflectra a Renflexis a	Subsequent continuing	Streamlined (9787)	s100 HSD Public	11423F
Infliximab 100mg injection, 1 vial	Inflectra a Renflexis a	Subsequent continuing	Streamlined (9732)	s100 HSD Private	11432Q

Infliximab PBS Listings Summary for Severe Crohn Disease

Form / Strength	Brand / a flag	Treatment Phase	Authority Level/Code	Program / Prescribing setting	PBS Item Code for Claiming
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Initial 1 (New patient) Initial 2 (Change or recommencement after break < 5 years) Initial 3 (Recommencement after break > 5 years) First continuing (Note – authority approval for sufficient therapy to complete the balance of supply may be requested by telephone)	Written	s100 HSD Public s100 HSD Private	5754W 9613Y
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a	Subsequent continuing	Written	S100 HSD Public S100 HSD Private	11389K 11399Y
Infliximab 100mg injection, 1 vial	Inflectra a Renflexis a	Subsequent continuing	Streamlined (9731)	S100 HSD Public	11400B
Infliximab 100mg injection, 1 vial	Inflectra a Renflexis a	Subsequent continuing	Streamlined (9733)	S100 HSD Private	11396T

Infliximab PBS Listings Summary for Acute Severe Ulcerative Colitis

Form / Strength	Brand / a flag	Treatment Phase	Authority Level/Code	Program / Prescribing setting	PBS Item Code for Claiming
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a		Streamlined (4524)	s100 HSD Public	10067W
Infliximab 100mg injection, 1 vial	Inflectra a Remicade a Renflexis a		Streamlined (9632)	s100 HSD Private	10057H