
PRIVACY NOTICE
PADCEV™ (enfortumab vedotin) Patient Access Initiative (PAI)

Astellas Pharma Australia Pty Ltd. ("Astellas") respects your right to privacy. This privacy notice explains who we are, how we collect, share, and use personal information about you, and how you can exercise your privacy rights when you participate in an Astellas early access program either as a treating physician submitting a request to Astellas or as a participating patient. If you have any questions or concerns about our use of your personal information or would like to exercise any of your rights, then please contact us using the details provided at the bottom of this Privacy Notice.

What does Astellas do?

Astellas is a global pharmaceutical business, whose ultimate parent company is headquartered in Tokyo, Japan. Our mission is to contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information about Astellas, please see our website at <https://www.astellas.com/>.

What personal information does Astellas collect and why?

Astellas needs to process the personal information of individuals requesting participation in the early access program for PADCEV™ (enfortumab vedotin) Patient Access Initiative (PAI) ("Program"). Individuals typically include the physicians who submit early access requests and the relevant patients for whom requests are submitted. Astellas may collect the personal information stated for the purposes below:

Types of personal information Astellas may collect	Purpose
Patient initials, date of birth, weight, health information related to program inclusion and exclusion criteria (e.g., treatment indication, previous therapy received, etc.)	We require this information to assess the eligibility of patients considered for treatment in the Program.
Clinician's (prescriber's) name, surname, prescriber's number, contact details (hospital address, contact number, email address)	We require this information to communicate with clinicians requesting therapy for their patients.

The clinician will submit a request for a patient to participate in the Program with the personal information mentioned above. The clinician will not transmit to Astellas any data that will directly identify any patient. The patient initials/patient code/date of birth and weight may be shared with Slade Health for the purpose of conducting the Program. The sponsor and its representatives will store the personal information in their secured electronic systems.

Astellas relies on a patient's explicit permission (or "consent") to use patient data for the purpose of assessing eligibility, . If a patient does not consent to the personal information being collected, shared, and used, the patient will not be able to take part in the Program and the request submitted by the treating clinician will not be considered. A patient's consent will be obtained by the clinician.

Astellas relies on its legal obligations arising from pharmacovigilance legislation to process personal information for safety reporting purposes.

Astellas relies also on its legitimate interest to process the personal information of clinician to run this Program.

How will personal information be used?

The treating clinician will use the patient personal information to fill out the relevant Patient Enrolment Form and submit it to Astellas. Astellas will then confirm if the patient is eligible to participate in the Program.

In case the patient, the treating clinician, or other person will submit an adverse event report to Astellas that includes patient personal information, such personal information will be used, where required, to report adverse events to local authorities. Where use of personal information for safety reporting to authorities is not required, such reports will be completed in an anonymous manner. Astellas will also retain information related to adverse events to assess the safety of our products.

Data retention

Astellas retains personal information collected for safety purposes for the life of the company since such information is important for public health reasons. The Program record will be kept by Astellas for 7 years. If the Program record is needed for a specific purpose, such as approval to market a medicinal product, it may be kept longer.

How does Astellas keep personal information secure?

We use appropriate technical and organizational measures to protect the personal information that we collect and process about participating individuals. The measures we use are designed to provide a level of security appropriate to the risk of processing the relevant personal information. Specific measures we use include storing the personal information in internal systems and intranet sites, which are protected and have restricted access only for certain users under the appropriate contractual and technical safeguards.

Who will be able to see the personal information processed?

The following entities/people may have access to personal information:

- The treating clinician, other health care professionals, and staff participating in this program.
- Astellas and its present or future affiliates will have access to personal information included in an adverse event reported to us.
- Local authorities and ethics committees in cases where we are required to submit or share such information based on legal requirements.
- Research, collaboration and licensing partners and/or service providers and authorized representatives of Astellas.
- Any competent law enforcement body, regulatory, government agency, court, or other third party where we believe disclosure is necessary (i) as a matter of applicable law or regulation, (ii) to exercise, establish or defend our legal rights, or (iii) to protect your vital interests or those of any other person.
- A potential buyer (and its agents and advisers) in connection with any proposed purchase, merger, or acquisition of any part of our business, provided that we inform the buyer it must use your personal information only for the purposes disclosed in this Privacy Notice.

Some of the parties above may not be located in the country of residence of the patient or the treating clinician. If such personal information is shared with another country, which may include a country outside of the Australia:

- data protection laws may not be as strict as in the country of residence,
- it may be shared with another party not listed above, and
- the people and organizations receiving the personal information may not be legally required to protect the privacy of your personal information.

Astellas is taking appropriate safeguards and measures to make sure that your personal information is protected. These include implementing special contract clauses, known as Standard Contractual Clauses, which protect transfers of personal information between companies in the Astellas group, which can be provided on request. Astellas is implementing similar appropriate safeguards and measures with third party service providers and partners, and further details can be provided upon request.

Can I see my own personal information?

Yes. You have the right to see and request a copy of your personal information for as long as we hold it.

What rights do I have?

In some countries, you may have certain data protection rights in accordance with applicable data protection laws. For example:

- You may be entitled to **access, correct, update, or request deletion** of your personal information by contacting us using the details provided under the “How to contact us” heading below.
- In addition, depending on the jurisdiction and the rights recognised by the applicable law, you may **object to us processing** your personal information, ask us to **restrict processing** your personal information or **request portability** of your personal information. Again, you can exercise these rights by contacting us using the details provided under the “How to contact us” heading below.
- Similarly, if we have collected and processed your personal information with your consent, then you can **withdraw your consent** at any time. If you wish to withdraw your consent you must notify your physician, and you will no longer be able to participate in the program. Withdrawing your consent will not affect the lawfulness of any processing we conducted prior to your withdrawal, nor will it affect processing of your personal information conducted in reliance on lawful processing grounds other than consent. Again, you can do so at any time by contacting us using the process and details provided under the “How to contact us” heading below. Any personal information that was collected from you until the time that you withdrew consent may continue to be used by the sponsor and its representatives where further use or continued storage is required to comply with a legal or regulatory obligation.
- In a number of countries, you have the **right to complain to a data protection authority** about our collection and use of your personal information. For more information, please contact your local data protection authority (Contact details for data protection authorities in the European Economic Area are available [here](#)).

We respond to all requests we receive from individuals wishing to exercise their data protection rights in accordance with applicable data protection laws.

How to contact us?

The data controller of your personal information processed for the purposes stated in this notice is Astellas Astellas Pharma Australia Pty Ltd. ABN 81 147 915 482. Suite 2.01, 2 Banfield Road, Macquarie Park, NSW 2113.

To exercise any of your privacy rights, or in case of any questions or concerns about our use of your personal information, please contact your treating clinician and/or our data protection officer using the following details: privacy@astellas.com or privacyofficer-au@astellas.com

Please note that your questions and requests can be addressed in the most efficient way if you refer those to your treating physician. Additionally, while Astellas does not wish to know your identity given the scientific nature of the Program, if you contact Astellas, your identity will be made known.
