IMFINZI®
durvalumab

GUIDE FOR HEALTHCARE PROFESSIONALS

CO-PAY PATIENT ACCESS PROGRAM

- Biliary Tract Cancer
- Muscle Invasive Bladder Cancer
- Locally Advanced Non-Small Cell Lung Cancer
- Extensive-Stage Small Cell Lung Cancer

For program support: AccessAZ@astrazeneca.com | 0800 965 233
Portal: www.AccessAZ.co.nz

AstraZeneca

PROGRAM OVERVIEW

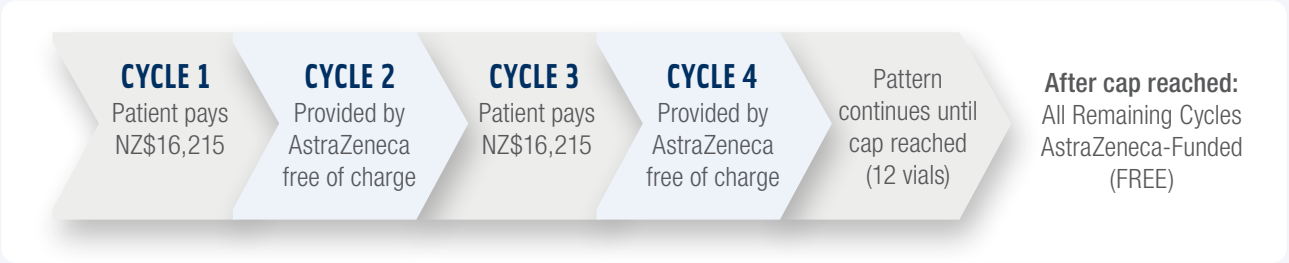
About the program

AstraZeneca supplies IMFINZI (durvalumab) through a Co-Pay Patient Access Program (PAP). For eligible adult patients prescribed IMFINZI, AstraZeneca funds alternating treatment cycles. Patients pay every other cycle starting with Cycle 1, up to a cap of 12 paid vials (equivalent to 4 patient-paid cycles). After the cap is reached, remaining eligible cycles are AstraZeneca-funded.

Important: The program provides financial assistance only; clinical decisions remain at the prescriber's discretion. Use must align with the IMFINZI Data Sheet. AstraZeneca has the right to cease or amend the program to new enrolments at any time. Participants will be notified of any changes.

Payment structure

- Alternating cycles: Patient pays cycles 1, 3, 5, 7. AstraZeneca funds cycles 2, 4, 6, 8
- Patient cap: 12 vials (4 cycles) = NZ$64,860 (incl. GST)
- After cap reached: All remaining cycles - IMFINZI provided by AstraZeneca
- Per cycle IMFINZI cost: 3 vials × NZ$5,405 = NZ$16,215



Note: Program covers IMFINZI supply only. Infusion, compounding, and administration costs remain patient/institution responsibility for all cycles.

Key contacts

General program enquiries and AccessAZ portal support

Email: AccessAZ@astrazeneca.com
Phone: 0800 965 233
Hours: Monday to Friday, 11am - 7pm NZST/NZDT
Website: www.AccessAZ.co.nz

AstraZeneca Medical Information

Online: https://contactazmedical.astrazeneca.com
Phone: 0800 684 432

Adverse event reporting

AstraZeneca continually monitors the safety profile of their products. To support this ongoing process, if a patient has experienced an adverse event (including any untoward medical occurrence), special situation (including a dose reduction or discontinuation due to an adverse event), or a product quality complaint, please report this to AstraZeneca:

- **Online:** https://contactazmedical.astrazeneca.com
- **Phone:** AstraZeneca Medical Information on 0800 684 432 or (09) 306 5650

Important: Mention with your report that the patient is participating in the IMFINZI Co-Pay PAP in New Zealand.

ELIGIBILITY & ENROLMENT

Core eligibility (all indications)

Patient must:

- ▶ Be aged ≥18 years
- ▶ Be eligible for NZ publicly funded healthcare
- ▶ Provide written consent (retain on file - do not send to AstraZeneca)
- ▶ Have no contraindications per IMFINZI Data Sheet
- ▶ Meet indication-specific clinical criteria (see pages 4-7)

Program duration

Treatment continues until disease progression, unacceptable toxicity, completion of planned treatment, national reimbursement becomes available

Enrolment process

Prescribers

Step 1: Register/Login at www.AccessAZ.co.nz (use AstraZeneca credentials or CPN/HPI number)

Step 2: Verify patient eligibility (core + indication-specific)

Step 3: Provide patient information and obtain written consent (retain on file)

Step 4: Complete online enrolment (nominate pharmacy)

Step 5: Issue prescription per institutional protocols

Pharmacists

Patient-paid cycles: Procure via wholesaler → Invoice patient → Submit proof of purchase to AccessAZ

AstraZeneca-funded cycles: Order via AccessAZ portal → Receive AstraZeneca shipment (free) → Dispense

Ongoing Management

Resupply

Prescribers: Confirm treatment continuation before each cycle via AccessAZ

Pharmacists: Verify cycle type (patient-paid vs AstraZeneca-funded) before dispensing

Discontinuation

Prescribers: Update AccessAZ portal immediately (My Patients → Select patient → Discontinue → Enter last treatment date)

Pharmacists: Will receive automatic notification (no action required)

Patient Resources

Download at www.AccessAZ.co.nz:

- ▶ IMFINZI PAP Patient Information & Consent Form (required - retain on file)
- ▶ IMFINZI Consumer Medicine Information

BILIARY TRACT CANCER

Patient Eligibility

Diagnosis: Locally advanced or metastatic biliary tract cancer (BTC)

Prior Therapy: Treatment-naïve for advanced/metastatic disease

Treatment: IMFINZI treatment must be or have been initiated with both gemcitabine and cisplatin

Treatment Regimen

Induction Phase (Up to 8 cycles)

- IMFINZI 1500 mg IV on Day 1 + gemcitabine and cisplatin (each administered on Days 1 and 8) every 3 weeks
- Administer IMFINZI prior to chemotherapy when given on the same day. Refer to the relevant Data Sheets for the appropriate chemotherapeutic agent for dosing information

Maintenance Phase (Until progression)

- IMFINZI 1500mg IV Q4W as monotherapy

Treatment Timeline

§Patients with a body weight of 30 kg or less must receive weight-based dosing, of IMFINZI at 20 mg/kg. In combination with chemotherapy dose IMFINZI every 3 weeks (21 days), followed by monotherapy at 20 mg/kg every 4 weeks until weight increases to greater than 30 kg.

Payment structure

Patient pays: Cycles 1, 3, 5, 7 (up to 12 vials)

After cap (12 vials): All remaining cycles AstraZeneca-funded

Full details: Page 2

Enrolment & Dispensing

Prescribers:

www.AccessAZ.co.nz → Register/Login → Enrol patient → Nominate pharmacy → Issue prescription

Pharmacists:

- Patient-paid cycles: Procure via wholesaler → Invoice patient → Submit proof of purchase to AccessAZ
- AstraZeneca-funded cycles: Order via AccessAZ portal → Receive AstraZeneca shipment (free) → Dispense

Important: During co-pay phase, submit proof of purchase to order AstraZeneca-funded cycles. After cap (12 vials), continue ordering via portal. Resupply is not automatic.

Q3W: Every 3 weeks; Q4W: Every 4 weeks

MUSCLE INVASIVE BLADDER CANCER

Patient Eligibility

Diagnosis: Confirmed muscle invasive bladder cancer (MIBC; T2-T4a, N0/1) planned for radical cystectomy

Treatment: IMFINZI treatment must be or have been initiated with both gemcitabine and cisplatin in the neoadjuvant phase

Treatment Regimen

Neoadjuvant Phase (4 cycles before surgery)

- ▶ IMFINZI IV 1500 mg + gemcitabine and cisplatin on Day 1, then gemcitabine on Day 8, every 3 weeks
- ▶ Administer IMFINZI prior to chemotherapy when given on the same day. Refer to the relevant Data Sheets for the appropriate chemotherapeutic agent for dosing information

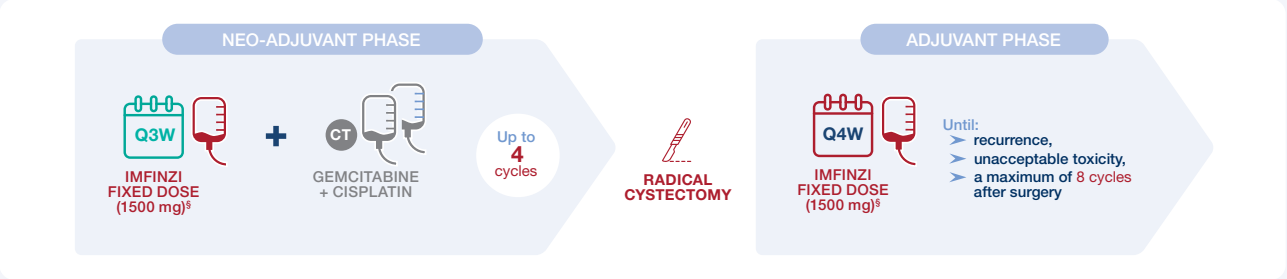
Surgery

- ▶ Radical cystectomy

Adjuvant Phase (Up to 8 cycles after surgery)

- ▶ IMFINZI 1500mg every 4 weeks

Treatment Timeline



§Patients with a body weight of 30kg or less must receive weight-based dosing of IMFINZI at 20mg/kg. In combination with chemotherapy, dose IMFINZI at 20mg/kg every 3 weeks (21 days) prior to surgery, followed by monotherapy at 20mg/kg every 4 weeks after surgery until weight increases to greater than 30kg.

Payment structure

Patient pays: Cycles 1, 3, 5, 7 (up to 12 vials)

After cap (12 vials): All remaining cycles AstraZeneca-funded

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Enrolment & Dispensing

Prescribers:

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Pharmacists:

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- ▶ AstraZeneca-funded cycles: Order via AccessAZ portal → Receive AstraZeneca shipment (free) → Dispense

Important: During co-pay phase, submit proof of purchase to order AstraZeneca-funded cycles. After cap (12 vials), continue ordering via portal. Resupply is not automatic.

Q3W: Every 3 weeks; Q4W: Every 4 weeks

LOCALLY ADVANCED NON-SMALL CELL LUNG CANCER

Patient Eligibility

Diagnosis: Confirmed diagnosis of locally advanced, unresectable non-small cell lung cancer (NSCLC) that has not progressed following platinum-based chemoradiation (CRT).

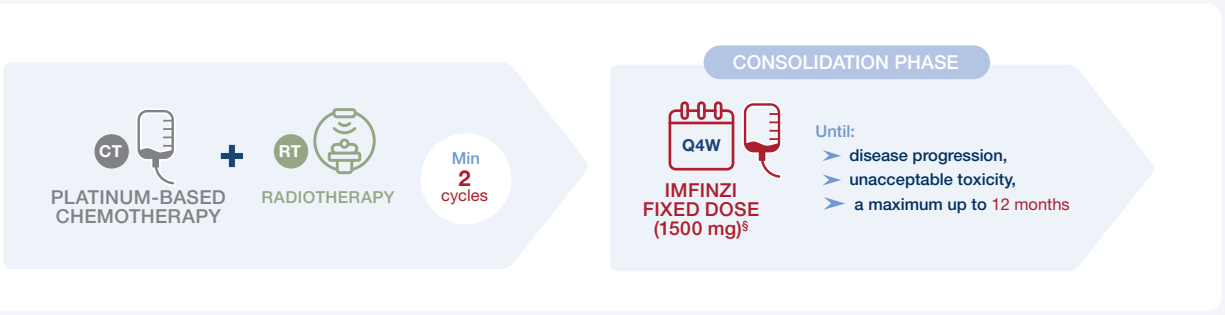
Treatment Regimen

▶ Platinum-based chemoradiotherapy

Consolidation

▶ IMFINZI 1500 mg every 4 weeks, for up to 12 months, or until disease progression or unacceptable toxicity

Treatment Timeline



§Patients with a body weight of 30 kg or less must receive weight-based dosing, equivalent to IMFINZI 10mg/kg every 2 weeks or 20 mg/kg every 4 weeks as monotherapy until weight increases to greater than 30 kg.

Payment structure

Patient pays: Cycles 1, 3, 5, 7 (up to 12 vials)

After cap (12 vials): All remaining cycles AstraZeneca-funded

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Enrolment & Dispensing

Prescribers:

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▶ AstraZeneca-funded cycles: Order via AccessAZ portal → Receive AstraZeneca shipment (free) → Dispense

Important: During co-pay phase, submit proof of purchase to order AstraZeneca-funded cycles. After cap (12 vials), continue ordering via portal. Resupply is not automatic.

Q3W: Every 3 weeks; Q4W: Every 4 weeks

EXTENSIVE-STAGE SMALL CELL LUNG CANCER

Patient Eligibility

Diagnosis: Confirmed diagnosis of extensive-stage small cell lung cancer (ES-SCLC).

Treatment Regimen

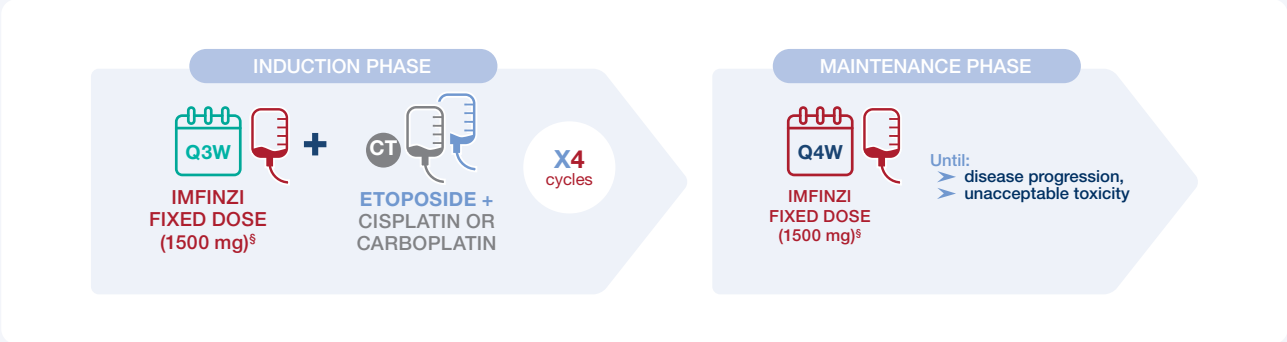
Induction phase (up to 4 cycles)

- ▶ IMFINZI 1500 mg + etoposide and either carboplatin or cisplatin every 3 weeks
- ▶ Administer IMFINZI prior to chemotherapy when given on the same day. Refer to the relevant Data Sheets for the appropriate chemotherapeutic agent for dosing information

Maintenance phase (until progression)

- ▶ IMFINZI: 1500mg IV Q4W as monotherapy

Treatment Timeline



§Patients with a body weight of 30kg or less must receive weight-based dosing, of IMFINZI at 20mg/kg. In combination with chemotherapy dose IMFINZI every 3 weeks (21 days), followed by monotherapy at 20 mg/kg every 4 weeks until weight increases to greater than 30kg

Payment structure

Patient pays: Cycles 1, 3, 5, 7 (up to 12 vials)

After cap (12 vials): All remaining cycles AstraZeneca-funded

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Enrolment & Dispensing

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Q3W: Every 3 weeks; Q4W: Every 4 weeks

FREQUENTLY ASKED QUESTIONS

IMFINZI® durvalumab

Will AstraZeneca collect data on patients enrolled in the program?

De-identified patient data (initials, date of birth and gender) will be collected for the purposes of administering the program. Further information on AstraZeneca's Privacy Policy is available at **https://www.azprivacy.astrazeneca.com/**

Using the AccessAZ portal

I'm having trouble using the portal. Who should I contact?

For help using the AccessAZ portal or to speak to someone, call the AccessAZ team on 0800 965 233 (Mon to Fri, 11am - 7pm NZST/NZDT).

BEFORE PRESCRIBING, PLEASE REVIEW FULL MEDSAFE APPROVED DATA SHEET AVAILABLE ON REQUEST FROM ASTRAZENECA ON +64 (9) 306 5650 OR https://www.medsafe.govt.nz/

IMFINZI® 50mg/mL, concentrated solution for infusion. IMFINZI (durvalumab) 120mg/2.4mL or 500mg/10mL, concentrated solution for infusion in a single-dose vial. Prescription Medicine. **Therapeutic Indications: Urothelial carcinoma:** in combination with cisplatin-based chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, is indicated for the treatment of adult patients with muscle invasive bladder cancer (MIBC). **Non-small cell lung cancer (NSCLC):** treatment of adult patients with locally advanced, unresectable NSCLC whose disease has not progressed following platinum-based chemoradiation therapy. **Small cell lung cancer (SCLC):** in combination with etoposide and either carboplatin or cisplatin for first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC). **Biliary Tract Cancer (BTC):** in combination with chemotherapy for treatment of patients with locally advanced or metastatic BTC. **Dosage and Administration:** IMFINZI is administered as an intravenous (IV) infusion over 1 hour. **MIBC:** 1500mg in combination with chemotherapy every 3 weeks for 4 cycles prior to surgery, followed by 1500 mg every 4 weeks as monotherapy for up to 8 cycles after surgery, until disease progression that precludes definitive surgery, recurrence, unacceptable toxicity, or a maximum of 8 cycles after surgery. Patients with a body weight of 30 kg or less must receive weight-based dosing of IMFINZI at 20 mg/kg. In combination with chemotherapy, dose IMFINZI at 20 mg/kg every 3 weeks prior to surgery, followed by monotherapy at 20 mg/kg every 4 weeks after surgery until weight increases to greater than 30 kg. **Locally advanced NSCLC:** Monotherapy, 10 mg/kg every 2 weeks, or 1500mg every 4 weeks, for one year or until confirmed disease progression or unacceptable toxicity. Patients with a body weight of 30 kg or less must receive weight-based dosing, equivalent to IMFINZI 10 mg/kg every 2 weeks or 20 mg/kg every 4 weeks as monotherapy until weight increases to greater than 30 kg. **ES-SCLC:** 1500mg in combination with chemotherapy every 3 weeks for 4 cycles, followed by 1500mg every 4 weeks as monotherapy until confirmed disease progression or unacceptable toxicity. Patients with a body weight of 30 kg or less must receive weight-based dosing, of IMFINZI at 20 mg/kg in combination with chemotherapy dose every 3 weeks (21 days), followed by monotherapy at 20 mg/kg every 4 weeks until weight increases to greater than 30 kg. **BTC:** 1500mg in combination with chemotherapy every 3 weeks, followed by 1500mg every 4 weeks as monotherapy until confirmed disease progression or unacceptable toxicity. Patients with a body weight of 30 kg or less must receive weight-based dosing, of IMFINZI at 20 mg/kg in combination with chemotherapy dose every 3 weeks, followed by monotherapy at 20 mg/kg every 4 weeks until weight increases to greater than 30 kg. Administer IMFINZI prior to chemotherapy when given on the same day. Refer to prescribing information of appropriate chemotherapeutic agent for dosing information. In general, withhold IMFINZI for Grade 2 or 3 adverse reactions. Permanently discontinue IMFINZI for lifethreatening (Grade 4) adverse reactions, recurrent severe (Grade 3) immune-mediated reactions that require systemic immuno-suppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating corticosteroids. For Grade 4 laboratory abnormalities, discontinuation of IMFINZI should be based on clinical signs/symptoms and clinical judgement. See full Data Sheet for recommended treatment modifications and specific management for adverse reactions. IMFINZI has not been studied in patients with severe renal or hepatic impairment.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. **Special warnings and precautions for use: Immune-mediated adverse reactions (imARs):** Immune checkpoint inhibitors, including IMFINZI, can cause severe and fatal imARs, which may involve any organ system. Patients should be monitored for signs and symptoms associated with imARs including: immune-mediated pneumonitis and radiation pneumonitis, hepatitis, colitis, immune-mediated endocrinopathies including hypothyroidism/hyperthyroidism/thyroiditis, adrenal insufficiency, type 1 diabetes mellitus, hypophysitis/hypopituitarism, nephritis, dermatological adverse reactions, myocarditis (which can be fatal); and other imARs, e.g. aseptic meningitis, haemolytic anaemia, immune thrombocytopenia, myasthenia gravis, myelitis transverse, myositis, polymyositis, rhabdomyolysis, Guillain-Barré syndrome, pancreatitis, immune-mediated arthritis, encephalitis and ocular inflammatory toxicity, including uveitis and keratitis. See Data Sheet for further information on monitoring and management recommendations for imARs. **Infusion related reactions:** Monitor patients for signs and symptoms, severe reactions have been reported. **Efficacy in patients with PD-L1 expression** <1%: efficacy may be different, see full Data Sheet. **Paediatric use:** safety and efficacy not established in patients less than 18 years. **Use in pregnancy:** Category D. Durvalumab has the potential to impact maintenance of pregnancy and may cause foetal harm. Not recommended during pregnancy; women of childbearing potential should use effective contraception during treatment and for at least 3 months after the last dose. **Breast-feeding:** lactating women should be advised not to breastfeed during treatment and for at least 3 months after the last dose. **Adverse Reactions:** The safety of IMFINZI as monotherapy is based on pooled data in 3006 patients from 9 studies across multiple tumour types. The safety of IMFINZI in combination with chemotherapy is based on data in 265 patients from the CASPIAN (SCLC) study,338 patients from the TOPAZ-1 (BTC) study and 530 patients from the NIAGARA (MIBC) study and was consistent with IMFINZI monotherapy and known chemotherapy safety profiles. The safety of IMFINZI in combination with chemotherapy as neoadjuvant treatment, is based on data in 401 patients from the AEGEAN (resectable NSCLC) study and was consistent with known IMFINZI monotherapy and known chemotherapy safety profiles. The safety of IMFINZI in combination with platinum-based chemotherapy followed by IMFINZI as monotherapy (N=235) or in combination with olaparib (N=238) is based on data in patients from the DUO-E (endometrial cancer) study. The safety profile was consistent with IMFINZI monotherapy and known olaparib and chemotherapy safety profiles, with PRCA identified as associated specifically when olaparib is added to IMFINZI in the maintenance phase. Very *Common (≥ 10%):* Cough/productive cough, abdominal pain, diarrhoea, hypothyroidism, rash, pruritus, pyrexia, upper respiratory tract infections. *Common (≥ 1%):* Pneumonitis, dysphonia, increased aspartate aminotransferase or alanine aminotransferase, hyperthyroidism, increased blood creatinine, dysuria, night sweats, peripheral oedema, pneumonia, oral candidiasis, dental and oral soft tissue infections, influenza, myalgia, infusion related reaction. See Data Sheet for other listed adverse reactions including immune-mediated adverse reactions.

IMFINZI is funded for locally advanced, unresectable non-small cell lung cancer under Special Authority criteria; a prescription charge will apply. Please refer to the Pharmaceutical Schedule. IMFINZI is not funded for other indications. Before prescribing IMFINZI, please read the manufacturer's Data Sheet available at www.medsafe.govt.nz.

AstraZeneca continually monitor the safety profile of their products. To support this ongoing process, and to adhere with local and global regulatory obligations, we must collect all reports of potential Adverse Events (AE), special situations, and product quality complaints, in relation to a patient potentially administered an AstraZeneca product. If we identify a potential report during our communications with you, this will be shared with their medical (pharmacovigilance) team. The information may be disclosed to local and overseas regulatory authorities or other third parties (such as those providing AE case processing activities, or license partners), for the purposes of meeting pharmacovigilance requirements.

DOP: May 2026, NZ-3097, TAPS MR13227, GCS.

AstraZeneca