



**PB 30 of 2024**

# **National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (April Update) Instrument 2024**

*National Health Act 1953*

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I, NIKOLAI TSYGANOV, Assistant Secretary, Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health and Aged Care, delegate of the Minister for Health and Aged Care, make this Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 27 March 2024

**NIKOLAI TSYGANOV**  
Assistant Secretary  
Pricing and PBS Policy Branch  
Technology Assessment and Access Division

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## 1 Name

- (1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (April Update) Instrument 2024*.
- (2) This instrument may also be cited as PB 30 of 2024.

## 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. <i>The whole of this instrument</i>	<i>1 April 2024</i>	<i>1 April 2024</i>

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

This instrument is made under subsection 100(2) of the *National Health Act 1953*.

## 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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## Schedule 1—Amendments

### *National Health (Highly Specialised Drugs Program) Special Arrangement 2021 (PB 27 of 2021)*

**[1] Part 1, Division 1, Section 6, definition for “medication for the treatment of HIV or AIDS”**

*substitute:*

***medication for the treatment of HIV or AIDS*** means any of the following:

- (a) abacavir;
- (b) abacavir with lamivudine;
- (c) atazanavir;
- (d) atazanavir with cobicistat;
- (e) azithromycin;
- (f) bictegravir with emtricitabine with tenofovir alafenamide;
- (g) cabotegravir;
- (h) cabotegravir and rilpivirine;
- (i) darunavir;
- (j) darunavir with cobicistat;
- (k) darunavir with cobicistat, emtricitabine and tenofovir alafenamide;
- (l) dolutegravir;
- (m) dolutegravir with abacavir and lamivudine;
- (n) dolutegravir with lamivudine;
- (o) dolutegravir with rilpivirine;
- (p) doxorubicin - pegylated liposomal;
- (q) emtricitabine with rilpivirine with tenofovir alafenamide;
- (r) emtricitabine with tenofovir alafenamide;
- (s) etravirine;
- (t) ganciclovir;
- (u) lamivudine;

- (v) lamivudine with zidovudine;
- (w) lopinavir with ritonavir;
- (x) maraviroc;
- (y) nevirapine;
- (z) raltegravir;
- (aa) rifabutin;
- (bb) rilpivirine;
- (cc) ritonavir;
- (dd) tenofovir;
- (ee) tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat;
- (ff) tenofovir with emtricitabine;
- (gg) tenofovir with emtricitabine and efavirenz;
- (hh) valganciclovir;
- (ii) zidovudine.

**[2] Schedule 1, omit entry for Abacavir with Lamivudine and Zidovudine**

**[3] Schedule 1, omit entry for Fosamprenavir**

**[4] Schedule 1, entry for Lopinavir with ritonavir**

*omit:*

Tablet 100 mg-25 mg	Oral	Kaletra	C4454 C4512	120	5
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**[5] Schedule 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

		ARX- MYCOPHENOLATE	C5554 C5795 C9691 C9693	300	5
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**[6] Schedule 1, entry for Nusinersen**

**(a) omit from the column headed "Circumstances": C13064**

- (b) omit from the column headed "Circumstances": **C15053**
- (c) insert in numerical order in the column headed "Circumstances": **C15066 C15069 C15112 C15116**

**[7] Schedule 1, entry for Pomalidomide in each of the forms: Capsule 1 mg; and Capsule 2 mg**

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Pomalidomide Sandoz C13746 C13755	See Schedule 2	See Schedule 2
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**[8] Schedule 1, entry for Risdiplam**

- (a) omit from the column headed "Circumstances": **C14424**
- (b) insert in numerical order in the column headed "Circumstances": **C15095**

**[9] Schedule 1, entry for Selinexor**

- (a) omit from the column headed "Circumstances" (all instances): **C13161**
- (b) omit from the column headed "Purposes" (Maximum Quantity: 32; Number of Repeats: 2): **P13161**

**[10] Schedule 1, entry for Tenofovir with emtricitabine in the form Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg**

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	TENOFVIR/EMTRICI C6985 C6986 TABINE 300/200 ARX	60	5
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**[11] Schedule 2, entry for Nusinersen [Maximum Quantity: 1 dose; Maximum Repeats: 0]**

- (a) omit from the column headed "Circumstances": **C13064**
- (b) insert in numerical order in the column headed "Circumstances": **C15069 C15112**

**[12] Schedule 2, entry for Nusinersen [Maximum Quantity: 1 dose; Maximum Repeats: 3]**

- (a) omit from the column headed "Circumstances": **C15053**
- (b) insert in numerical order in the column headed "Circumstances": **C15066 C15116**

**[13] Schedule 2, entry for Risdiplam [Maximum Quantity: 1; Maximum Repeats: 5]**

omit from the column headed "Circumstances": **C14424** substitute: **C15095**

[14] Schedule 3, omit entry for Abacavir with Lamivudine and Zidovudine

[15] Schedule 3, omit entry for Fosamprenavir

[16] Schedule 3, entry for Nusinersen

(a) omit:

	C13064		<p>Spinal muscular atrophy (SMA) Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA listing Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS-indication has been for gene therapy. Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition; AND The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND The treatment must be given concomitantly with best supportive care for this condition; AND The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug. Patient must have been 18 years of age or younger at the time of initial treatment with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.</p>	Compliance with Written Authority Required procedures
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(b) omit:

	C15053		<p>Pre-symptomatic spinal muscular atrophy (SMA) Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) - Loading doses Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.</p>	Compliance with Written Authority Required procedures
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			<p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; OR</p> <p>The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene; AND</p> <p>The condition must be pre-symptomatic; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; AND</p> <p>Patient must be untreated with gene therapy.</p> <p>Patient must be aged under 36 months prior to commencing treatment.</p> <p>Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:</p> <p>(i) confirmation of genetic diagnosis of SMA; and</p> <p>(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)</p>	
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**(c)** insert in numerical order after existing text:

	C15066		<p>Pre-symptomatic spinal muscular atrophy (SMA)</p> <p>Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 1 or 2 copies of the SMN2 gene - Loading doses</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this</p>	Compliance with Written Authority Required procedures
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		<p>restriction; AND  Patient must be untreated with gene therapy.  Patient must be aged under 36 months prior to commencing treatment.  Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:  (a) a completed authority prescription form; and  (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:  (i) confirmation of genetic diagnosis of SMA; and  (ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)</p>	
	C15069	<p>Spinal muscular atrophy (SMA)  Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) listing  Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND  Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS-indication has been for gene therapy.  Patient must have previously received PBS-subsidised treatment with this drug for this condition;  OR  Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition;  AND  The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND  The treatment must be given concomitantly with best supportive care for this condition; AND  The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.  Patient must have been 18 years of age or younger at the time of initial treatment with this drug.  Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.  In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.</p>	Compliance with Written Authority Required procedures
	C15112	<p>Spinal muscular atrophy (SMA)  Continuing/maintenance treatment of a patient commenced on this drug under the pre-symptomatic SMA (3 copies of the SMN2 gene) listing  Must be treated by a specialist medical practitioner experienced in the diagnosis and management</p>	Compliance with Written Authority Required procedures

		<p>of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND</p> <p>Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS-indication has been for gene therapy.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR</p> <p>Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition; AND</p> <p>The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.</p> <p>Patient must have been 18 years of age or younger at the time of initial treatment with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.</p>	
	C15116	<p>Pre-symptomatic spinal muscular atrophy (SMA)</p> <p>Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene - Loading doses</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.</p> <p>The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR</p> <p>The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene; AND</p> <p>The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition; AND</p> <p>The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction; AND</p> <p>Patient must be untreated with gene therapy.</p> <p>Patient must be aged under 36 months prior to commencing treatment.</p> <p>Application for authorisation of initial treatment must be in writing (lodged via postal service or</p>	Compliance with Written Authority Required procedures

			<p>electronic upload) and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:</p> <p>(i) confirmation of genetic diagnosis of SMA; and</p> <p>(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)</p>	
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**[17] Schedule 3, entry for Risdiplam**

**(a) omit:**

	C14424		<p>Spinal muscular atrophy (SMA)</p> <p>Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR</p> <p>Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition; AND</p> <p>The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition; AND</p> <p>The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug; AND</p> <p>The treatment must be given concomitantly with best supportive care for this condition.</p> <p>Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic; AND</p> <p>Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS-indication has been for gene therapy.</p> <p>Patient must have been 18 years of age or younger at the time of initial treatment with this drug.</p> <p>Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.</p> <p>In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.</p> <p>The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.</p> <p>The approved Product Information recommended dosing is as follows:</p> <p>(i) 16 days to less than 2 months of age: 0.15 mg/kg</p> <p>(ii) 2 months to less than 2 years of age: 0.20 mg/kg</p> <p>(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg</p> <p>(iv) 2 years of age and older weighing 20 kg or more: 5 mg</p> <p>In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to</p>	Compliance with Written Authority Required procedures
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			(iv), prescribe up to: 1 unit where (i) applies; 2 units where (ii) applies; 3 units where (iii) applies; 3 units where (iv) applies.	
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**(b)** insert in numerical order after existing text:

	C15095		<p>Spinal muscular atrophy (SMA) Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition; AND The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition; AND The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug; AND The treatment must be given concomitantly with best supportive care for this condition. Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic; AND Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS-indication has been for gene therapy. Patient must have been 18 years of age or younger at the time of initial treatment with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required. The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing. The approved Product Information recommended dosing is as follows: (i) 16 days to less than 2 months of age: 0.15 mg/kg (ii) 2 months to less than 2 years of age: 0.20 mg/kg (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg (iv) 2 years of age and older weighing 20 kg or more: 5 mg In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to: 1 unit where (i) applies; 2 units where (ii) applies; 3 units where (iii) applies; 3 units where (iv) applies.</p>	Compliance with Written Authority Required procedures
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**[18] Schedule 3, entry for Selinexor**

*omit:*

	C13161	P13161	<p>Relapsed and/or refractory multiple myeloma  Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 160 mg per week  Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022; AND  The treatment must be in combination with dexamethasone; AND  Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition; AND  Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody; AND  Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.  Progressive disease is defined as at least 1 of the following:  (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or  (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or  (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or  (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or  (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or  (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).  Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	Compliance with Authority Required procedures
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