



California Office of Statewide Health Planning and Development (OSHPD)  
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April 23, 2019

Re: Drug Price Increase Notification for SAMSCA® (tolvaptan)

To Whom It May Concern:

In accordance with California Senate Bill 17 (Chapter 603, Statutes of 2017), Prescription Drug Pricing for Purchasers, and the California Health and Safety Code, § 127679, below please find the information a drug manufacturer is required to report, beginning April 1, 2019, regarding an existing prescription drug whose cumulative wholesale acquisition cost has increased more than 16 percent within the previous two calendar years.

**Section 1: WAC Increase**

1	NDC	59148002050	59148002150
2	Drug Product Description	SAMSCA® (tolvaptan) 15 mg tablets, blister pack of 10	SAMSCA® (tolvaptan) 30 mg tablets, blister pack of 10
3	WAC Effective Date	01/15/2019	01/15/2019
4	WAC Increase Amount	\$214.67	\$222.69
5	WAC After Increase	\$4,507.97	\$4,676.49
6	Patent Expiration Date	see comments below	see comments below
7	Drug Source Type	Single Source Drug	Single Source Drug
8	Unit Volume in US	Otsuka does not believe this information is in the public domain or otherwise publicly available. As a result, Otsuka is limiting its response pursuant to Cal. Health and Safety Code § 127679 (b).	
9	Unit Sales Volume Non- Public Indicator	Non Public	Non Public
10	Cost Increase Factors	Please see comments below.	
11	Cost Increase Factors Non-Public Indicator	Non Public	Non Public
12	Change/Improvement Description	None	None

Otsuka America Pharmaceutical, Inc.

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13	Change/Improvement Description Non-Public Indicator	Non Public	Non-Public
14	Acquisition Date	N/A	N/A
15	Company Acquired From	N/A	N/A
16	Acquisition Price	N/A	N/A
17	Acquisition Price Non- Public Indicator	N/A	N/A
18	Acquisition Price Comment	N/A	N/A
19	WAC at Acquisition	N/A	N/A
20	Year Drug Introduced to	N/A	N/A
21	WAC at Intro to Market	N/A	N/A
22	General Comments	Please see below.	

### Patent Expiration Date

Otsuka has two applicable patent expiration dates for tolvaptan:

- 5,753,677 - patent expiration date of 5/19/2020
- 8,501,730 - patent expiration date of 9/01/2026

### Cost Increase Factors

Otsuka is committed to making responsible pricing determinations for our products, including SAMSCA®, and in so doing we consider a range of factors.

Otsuka continues to concentrate on areas of unmet medical need in mental health, and cardio-renal. As a general matter, our WAC determinations are influenced by research and development costs (including investments in product and portfolio innovation); manufacturing, distribution, and regulatory costs; market and competitive factors; downstream demands for price concessions/rebates; value to patients and the health care system; and access and affordability.

Pricing decisions at Otsuka are made at the executive level in adherence with all federal and state laws. These decisions and underlying considerations are proprietary, and Otsuka does not believe this information is in the public domain or otherwise publicly available. As a result, Otsuka is limiting its response pursuant to Cal. Health and Safety Code § 127679 (b).

*(cont'd)*

**Section 2: Five-Year History**

NDC	WAC EFFECTIVE DATE	WAC INCREASE AMOUNT	WAC AFTER INCREASE
59148002050	1/15/2019	\$214.67	\$4,507.97
59148002050	1/1/2018	\$386.75	\$4,293.30
59148002050	7/1/2017	\$221.13	\$3,906.55
59148002050	1/1/2017	\$107.34	\$3,685.42
59148002050	1/1/2016	\$234.08	\$3,578.08
59148002050	6/15/2015	\$219.00	\$3,344.00
59148002150	1/15/2019	\$222.69	\$4,676.49
59148002150	1/1/2018	\$401.21	\$4,453.80
59148002150	7/1/2017	\$229.39	\$4,052.59
59148002150	1/1/2017	\$111.36	\$3,823.20
59148002150	1/1/2016	\$367.84	\$3,711.84
59148002150	6/15/2015	\$219.00	\$3,344.00

If additional information is required please contact [OAPIDrugPricing@otsuka-us.com](mailto:OAPIDrugPricing@otsuka-us.com).