Price for Xtandi 40 mg tab or capsule in high income countries

Country	Date	Price per unit in USD	2021 GNP per capita in USD (World Bank Atlas Method)	Annual cost of treatment in USD
Australia	Apr , 2023	$21.16	$57,170	$30,898
Canada	Apr , 2023	$21.13	$48,310	$30,847
Denmark	Apr , 2023	$35.13	$68,300	$51,287
Finland	Apr , 2023	$31.89	$53,510	$46,564
France	Apr , 2023	$29.00	$44,160	$42,333
Germany	Apr , 2023	$31.24	$51,660	$45,606
Japan	May , 2021	$21.64	$42,650	$31,593
Netherlands	Apr , 2023	$32.59	$55,200	$47,585
Sweden	Apr , 2023	$22.03	$59,540	$32,169
Switzerland (inc VAT)	Apr , 2023	$31.64	$90,600	$46,187
UK	Apr , 2023	$30.28	$44,480	$44,204
Saudi Arabia	Apr , 2023	$22.90	$21,540	$33,435
USA, AWP	Jan , 2023	$136.50	$70,930	$199,290
USA, WAC	Jan , 2023	$113.75	$70,930	$166,075
USA, Medicare Part D	Fy 2021	$112.28	$70,930	$163,929

WAC is wholesale acquisition cost. AWP is average wholesale price

Notes:

The standard dose is four 40 mg capsules or tabs per day, or 1,460 per year.

Prices have increased steadily in the US. The fiscal year 2012 Medicare price was $63.72. In fiscal year 2016, the year of the first Xtandi petition, the price was $76.69.

In most high income countries, prices have fallen over the years, making the disparities in prices more stark

See: drugdatabase.info

Key provisions in Bayh-Dole Act

35 U.S. Code §200. Policy and objective

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and **protect the public against nonuse or unreasonable use of inventions**; and to minimize the costs of administering policies in this area.

35 U.S.Code §201. Definitions

(f) The term “practical application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations **available to the public on reasonable terms.**

Additional context: S. 3496, 95th Congress, first version by Dole and Bayh, in 1978.

"(e) The term 'practical application' means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or government regulations **available to the public on reasonable terms from the subject inventor or licensee or assignee of the subject inventor.**

35 U.S. Code § 202 - Disposition of rights

(c)Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:
(4)With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: . . .

35 U.S. Code § 209 - Licensing federally owned inventions

(d)Terms and Conditions.—Any licenses granted under section 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions—
(1)retaining a nontransferable, irrevocable, paid-up license for any Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States;

March 2023 NIH decision and appeal

March 21, 2023 NIH letter: NIH's analyses in response to the petition request have found Xtandi to be widely available to the public on the market. In addition, given the remaining patent life and the lengthy administrative process involved for a march-in proceeding, NIH does not believe that use of the march-in authority would be an effective means of lowering the price of the drug. For these reasons, NIH has determined that initiation of a march-in proceeding is not warranted in this case. This decision is consistent with NIH's determination in 2016, in which KEI and the Union for Affordable Cancer Treatment requested NIH and the Department of Defense march-in based on the price of Xtandi, but each declined./7,8/ In responding to the march-in request for Xtandi in 2016, NIH explained that, consistent with march-in determinations for Cell Pro (1997), Norvir (2004, 2013) and Xalatan (2004), /9/ **practical application is evidenced by the "manufacture, practice, and operation" of the invention and the invention's "availability to and use by the public…." A**stellas, the maker of Xtandi, estimates that more than 200,000 patients were treated with Xtandi from 2012 to 2021. /10/ **Therefore, the patent owner, the University of California, does not fail the requirement for bringing Xtandi to practical application, as the drug is manufactured and on the market in the manner of other prescription drugs.**

March23, 2023 appeal: The NIH has repeatedly demonstrated its unwillingness to even acknowledge that the Bayh-Dole Act includes an obligation to make products invented with federal funds "available to the public on reasonable terms." . .

The petition focused on a single issue: the reasonableness of charging US cancer patients 3 to 6 times more than residents of other high-income countries for the drug Xtandi. . ..

The central issue in the case has always been about the last seven words in the definition: "available to the public on reasonable terms." . . .

Absent from the [NIH] letter is any mention of "reasonable terms" or the price for which Xtandi is sold in the U.S. The quotes from Dr. Tabaks' letter do not track the statute or the regulations on march-in rights, and specifically, omit the central issue in the case, that the patent holder must make the product "available to the public on reasonable terms." This blatant omission cannot and should not be ignored.

The 'clock has run" argument might have some weight if NIH had not totally ignored the federal government's parallel authority, cited by petitioners, to use its royalty-free rights in the patents under 35 USC § 202(c)(4), which gives the US government a "paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world." This license, which does not even require the payment of royalties to Astellas, gives the US government the legal ability to authorize a generic version of Xtandi at any time, the only issue being a question of the breadth of the authorization.