Universalidade, equidade e integralidade na assistência farmacêutica

Daniel Wei Liang Wang

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Country	Proportion of TPE (UI)							
	Sofosbuvir Treatment Coverage				Ledipasvir/Sofosbuvir Treatment Coverage			
	10%	50%	75%	100%	10%	50%	75%	100%
Poland	16.2% (11.1%, 40.6%)	81.1% (55.4%, 203.0%)	121.6% (83.1%, 304.5%)	162.2% (110.9%, 405.9%)	19.1% (13.0%, 45.1%)	95.3% (65.1%, 225.5%)	142.9% (97.7%, 338.3%)	190.5% (130.3%, 451.0%)
New Zealand	15.5% (8.9%, 26.8%)	77.5% (44.5%, 133.8%)	116.3% (66.8%, 200.6%)	155.0% (89.0%, 267.5%)	15.1% (9.3%, 26.1%)	75.6% (46.4%, 130.4%)	113.4% (69.7%, 195.6%)	151.2% (92.9%, 260.8%)
Portugal	13.3% (8.7%, 23.0%)	66.6% (43.6%, 114.9%)	99.9% (65.3%, 172.3%)	133.2% (87.1%, 229.8%)	16.5% (9.9%, 28.5%)	82.6% (49.4%, 142.6%)	124.0% (74.2%, 213.9%)	165.3% (98.9%, 285.2%)
Italy	11.1% (7.5%, 21.4%)	55.6% (37.4%, 107.1%)	83.4% (56.1%, 160.7%)	111.1% (74.8%, 214.3%)	12.3% (8.5%, 25.2%)	61.7% (42.5%, 125.9%)	92.6% (63.7%, 188.8%)	123.5% (84.9%, 251.8%)
Spain	10.0% (5.4%, 16.7%)	50.0% (27.1%, 83.3%)	75.0% (40.7%, 125.0%)	100.0% (54.3%, 166.7%)	11.2% (5.4%, 17.0%)	56.0% (26.9%, 85.2%)	83.9% (40.3%, 127.9%)	111.9% (53.7%, 170.5%)
Greece	9.7% (4.8%, 15.2%)	48.3% (23.9%, 76.2%)	72.4% (35.8%, 114.3%)	96.6% (47.7%, 152.4%)	Not available			
Slovakia	7.0% (4.4%, 9.9%)	35.2% (22.0%, 49.5%)	52.8% (33.0%, 74.3%)	70.4% (44.0%, 99.0%)	Not available			
Japan	5.2% (2.9%, 9.5%)	26.1% (14.6%, 47.7%)	39.1% (21.9%, 71.6%)	52.1% (29.2%, 95.5%)	6.8% (3.9%, 11.1%)	33.8% (19.5%, 55.5%)	50.7% (29.3%, 83.2%)	67.6% (39.0%, 110.9%)
Switzerland	5.2% (2.9%, 9.0%)	26.0% (14.3%, 44.8%)	39.0% (21.5%, 67.2%)	52.0% (28.6%, 89.6%)	5.6% (2.6%, 6.7%)	28.1% (12.9%, 33.7%)	42.2% (19.4%, 50.6%)	56.3% (25.8%, 67.5%)
United States	5.2% (2.6%, 8.8%)	25.9% (13.2%, 43.9%)	38.8% (19.8%, 65.9%)	51.7% (26.4%, 87.9%)	5.8% (2.9%, 9.7%)	29.1% (14.7%, 48.6%)	43.6% (22.1%, 72.8%)	58.2% (29.4%, 97.1%)
Luxembourg	5.1% (2.6%, 7.9%)	25.5% (13.1%, 39.5%)	38.2% (19.6%, 59.3%)	50.9% (26.1%, 79.1%)	6.4% (3.6%, 10.7%)	32.1% (18.1%, 53.7%)	48.2% (27.1%, 80.6%)	64.3% (36.1%, 107.4%)
Ireland	4.2% (2.5%, 6.2%)	21.2% (12.7%, 31.1%)	31.8% (19.1%, 46.6%)	42.4% (25.4%, 62.2%)	Not available			
Denmark	3.9% (2.3%, 6.1%)	19.6% (11.5%, 30.3%)	29.4% (17.3%, 45.4%)	39.2% (23.1%, 60.6%)	5.9% (3.2%, 10.3%)	29.3% (15.8%, 51.3%)	43.9% (23.7%, 76.9%)	58.6% (31.6%, 102.6%)
Belgium	3.1% (1.9%, 5.0%)	15.6% (9.6%, 24.9%)	23.5% (14.3%, 37.3%)	31.3% (19.1%, 49.8%)	Not available			
Norway	3.0% (1.8%, 4.1%)	15.2% (8.8%, 20.6%)	22.8% (13.3%, 30.9%)	30.4% (17.7%, 41.2%)	3.4% (2.3%, 5.8%)	16.9% (11.3%, 29.1%)	25.4% (16.9%, 43.7%)	33.8% (22.5%, 58.3%)
Canada	3.0% (1.8%, 3.9%)	14.9% (8.8%, 19.6%)	22.4% (13.2%, 29.4%)	29.9% (17.6%, 39.2%)	3.6% (2.3%, 5.9%)	18.2% (11.4%, 29.3%)	27.3% (17.1%, 43.9%)	36.4% (22.8%, 58.6%)
United Kingdom	3.0% (1.6%, 3.8%)	14.9% (8.1%, 19.2%)	22.3% (12.2%, 28.8%)	29.7% (16.2%, 38.3%)	3.3% (2.0%, 4.3%)	16.6% (9.9%, 21.3%)	24.8% (14.8%, 32.0%)	33.1% (19.7%, 42.7%)
Finland	2.9% (1.6%, 3.5%)	14.4% (8.1%, 17.7%)	21.6% (12.2%, 26.6%)	28.8% (16.2%, 35.5%)	3.4% (2.0%, 4.3%)	16.9% (9.9%, 21.6%)	25.3% (14.8%, 32.4%)	33.8% (19.8%, 43.2%)
Sweden	2.7% (1.4%, 3.4%)	13.5% (6.9%, 17.1%)	20.3% (10.4%, 25.6%)	27.0% (13.8%, 34.2%)	3.2% (1.9%, 4.2%)	15.9% (9.5%, 21.2%)	23.9% (14.2%, 31.9%)	31.9% (19.0%, 42.5%)
Austria	2.1% (1.1%, 3.4%)	10.7% (5.7%, 17.0%)	16.1% (8.5%, 25.5%)	21.4% (11.4%, 34.1%)	2.4% (1.4%, 3.3%)	12.0% (7.1%, 16.5%)	18.0% (10.6%, 24.7%)	24.0% (14.2%, 32.9%)
Germany	2.1% (0.6%, 2.9%)	10.5% (2.9%, 14.7%)	15.8% (4.4%, 22.0%)	21.1% (5.9%, 29.4%)	2.6% (1.5%, 3.8%)	13.1% (7.7%, 19.2%)	19.7% (11.6%, 28.8%)	26.3% (15.5%, 38.3%)
France	1.8% (0.4%, 2.8%)	9.0% (2.0%, 13.9%)	13.4% (3.1%, 20.8%)	17.9% (4.1%, 27.7%)	2.0% (0.8%, 3.3%)	10.0% (3.9%, 16.3%)	15.1% (5.9%, 24.5%)	20.1% (7.9%, 32.6%)
Netherlands	1.0% (0.4%, 1.8%)	5.2% (2.0%, 9.0%)	7.9% (3.0%, 13.6%)	10.5% (4.0%, 18.1%)	1.4% (0.4%, 2.4%)	7.0% (2.2%, 12.1%)	10.5% (3.3%, 18.1%)	14.0% (4.4%, 24.2%)

Iyengar S, Tay-Teo K, Vogler S, Beyer P, Wiktor S, et al. (2016) Prices, Costs, and Affordability of New Medicines for Hepatitis C in 30 Countries: An Economic Analysis. PLoS Med 13(5): e1002032. doi:10.1371/journal.pmed.1002032

"the cost of cancer care has risen appreciably in recent years, and is projected to increase at an unsustainable rate if left to pharmaceutical companies, with the prices of new cancer medicines increasing up to 10-fold during the past 10 years and likely to continue" (p.103)

Table 12. Examples of high prices for cancer drugs (acquisition costs) with often limited health gain

Drug	Total drug acquisition costs per patient and estimated increase in survival
Cetuximab	• US$ 80 352 • 1.2 months (non-small cell lung carcinoma)
Bevacizumab	• US$ 90 816 • 1.5 months (metastatic breast cancer – not statistically significant)
Erlotinib	• US$ 15 752 • 10 days (pancreatic cancer)
Sorafenib	• US$ 34 373 • 2.7 months (renal cell carcinoma)

Source: Fojo & Grady *(12)*.

"Conclusions This systematic evaluation of oncology approvals by the EMA in 2009-13 shows that most drugs entered the market without evidence of benefit on survival or quality of life. At a minimum of 3.3 years after market entry, there was still no conclusive evidence that these drugs either extended or improved life for most cancer indications. When there were survival gains over existing treatment options or placebo, they were often marginal."

"Among the 12 new anticancer drugs approved by the FDA in 2012, only one provides survival gains that exceed two months". (p.37)

SCIENCE TRANSLATIONAL MEDICINE | FOCUS

DRUG DEVELOPMENT

Efficacy and costs of spinal muscular atrophy drugs

Jonathan J. Darrow[1]*, Monica Sharma[2], Mansa Shroff[3], Anita K. Wagner[4,5]

Evaluating the benefits, risks, and costs of two drugs to treat spinal muscular atrophy raises questions about the future of rare disease medicines.

"FDA documents reveal benefits more modest than these accolades and costs suggest... long-term efficacy is unknown". (p.1-2)

"If the estimated 15 new cell and gene therapy treatments per year impose similar costs for similar population sizes […] annual costs would reach $195 billion to treat 97,500 patients or 0.03% of the U.S. population" (p.3).

"Although the progress to develop treatments for SMA is encouraging, the expected proliferation of high-cost treatments that may sometimes offer only modest benefits requires immediate legislative attention" (p.3).

Ministério da Saúde
Secretaria Executiva
Gabinete da Secretaria Executiva
Coordenação-Geral de Gestão de Demandas Judiciais em Saúde
Coordenação de Análise Médica e Farmacêutica de Demandas Judiciais

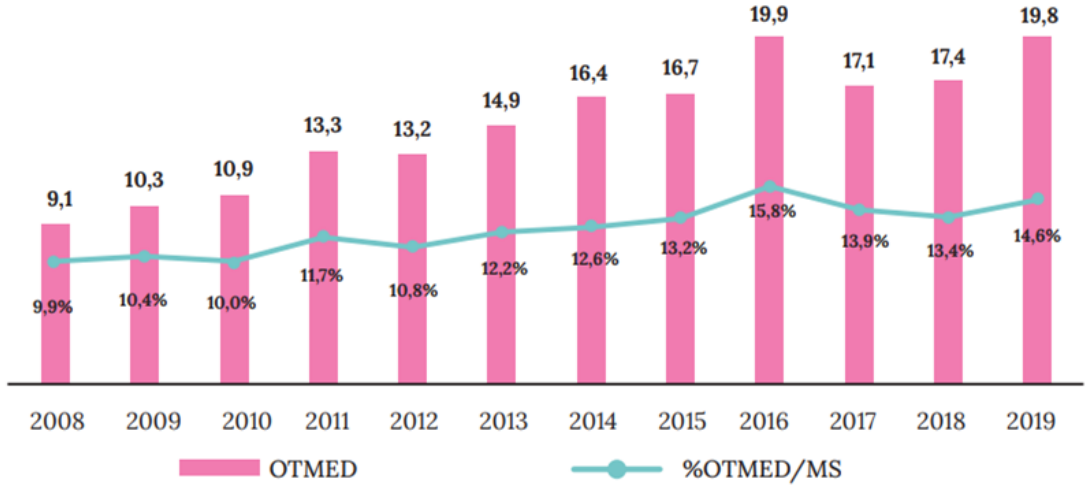
NOTA TÉCNICA Nº 1517/2020-CGJUD/COMFAD/CGJUD/SE/GAB/SE/MS

	gasto anual	numero de pacientes atendidos
medicamentos geridos pelo CEAF 2019	4,5 bilhõoes de reais	2,5 millhões de pacientes
previsão para Zolgensma no primeiro ano	4,9 bilhões de reais	450 pacientes

Gastos com medicamentos do Ministério da Saúde

(em bilhões de reais corrigidos a preços de 2019)

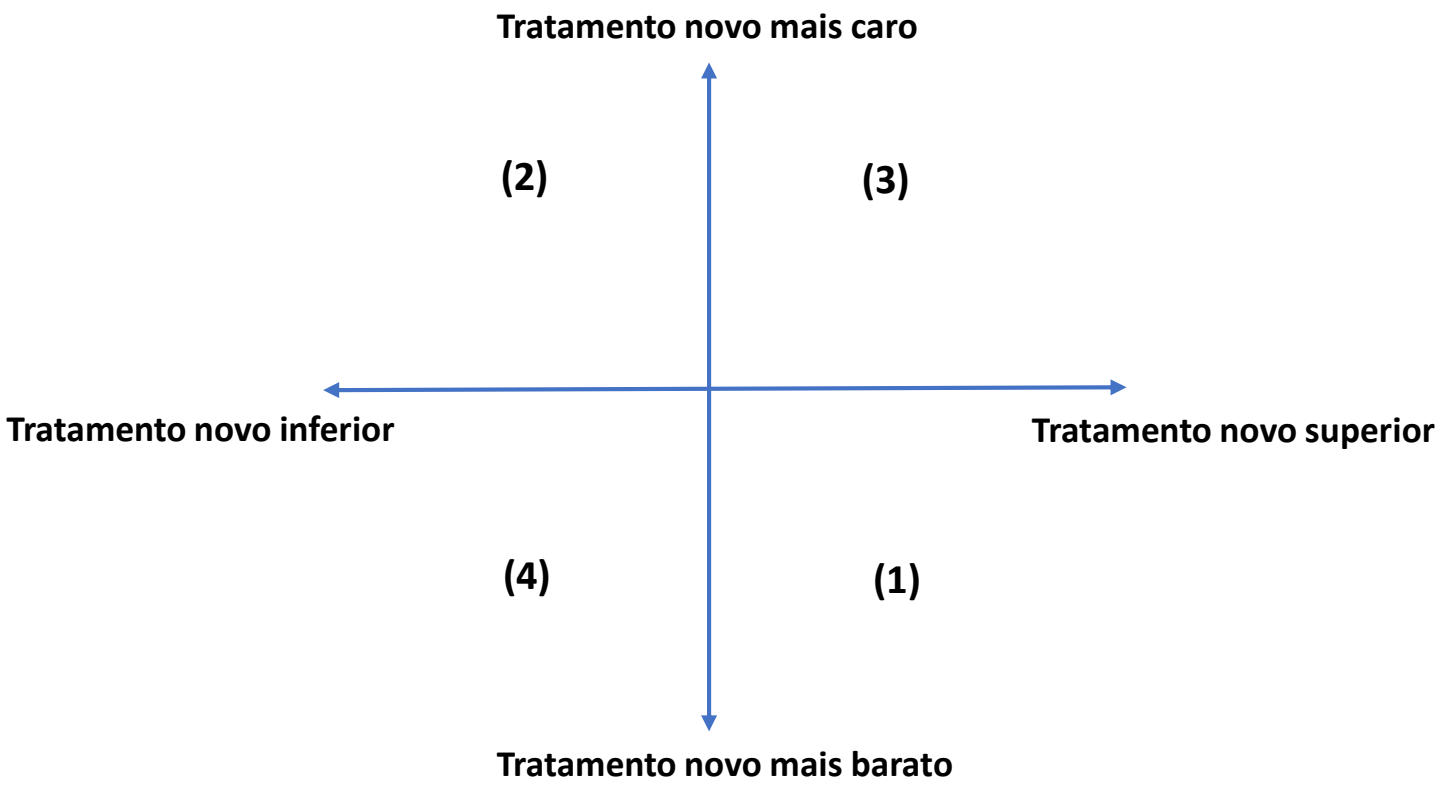
A execução financeira do MS com medicamentos volta a subir em 2019, chegando a R$ 19,8 bilhões após uma estabilidade nos anos anteriores e se equipara ao pico de 2016. Esse gasto mais que dobrou quando comparado a 2008, enquanto o do Ministério cresceu cerca de 42% em termos reais. Assim, ele consome uma fatia cada vez maior do orçamento da saúde.



Alocação de recursos e controle de gastos na Inglaterra

National Institute for Health and Care Excellence – NICE

- Análise de custo-efetividade
- Limite de £30.000/QALY

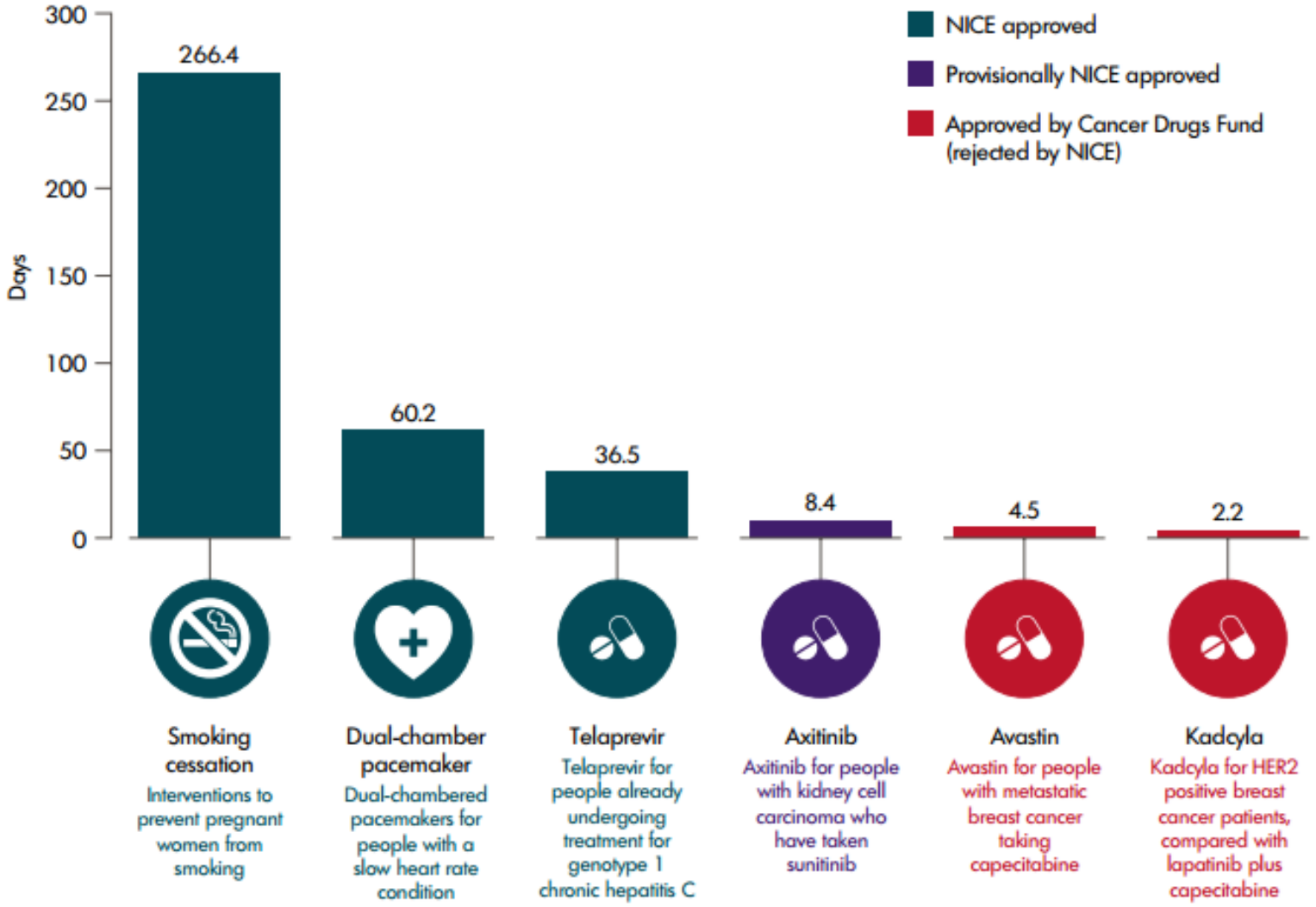


TRATAMENTO	EXPECTATIVA DE VIDA	QUALIDADE DE VIDA	QALY	£
A	**10**	**0.6**	**6**	
B	**5**	**0.4**	**2**	
Diferença			**4**	

TRATAMENTO	EXPECTATIVA DE VIDA	QUALIDADE DE VIDA	QALY	£
A	**10**	**0.6**	**6**	**50.000**
B	**5**	**0.4**	**2**	**10.000**
Diferença			**4**	**40.000**

TRATAMENTO	EXPECTATIVA DE VIDA	QUALIDADE DE VIDA	QALY	£
A	**6**	**0.5**	**3**	**50.000**
B	**5**	**0.4**	**2**	**10.000**
Diferença			**1**	**40.000**

FIGURE 2: ADDITIONAL DAYS OF QUALITY-ADJUSTED LIFE PER £1,000 FOR SELECTED INTERVENTIONS



Source: Nuffield Trust. Rationing in the NHS, 2015

PROJETO DE LEI Nº , DE 2021
(Do Sr. Guilherme Mussi)

Reconhece ao portad
Espinhal (AME) o di
gênica no âmbito d
Saúde (SUS), na form

O Congresso Nacional decreta:

Art. 1º Esta lei reconhece e regula, em âmbito nacional,
de Atrofia Muscular Espinhal (AME) receber terapia gênica
Único de Saúde (SUS).

Parágrafo único. Na ausência de normas e regras da
setembro de 1990, que regulem terapias gênicas de alto custo, as
lhes serão aplicadas supletiva e subsidiariamente.

Art. 2º É direito do portador de Atrofia Muscular Espin
âmbito do Sistema Único de Saúde (SUS), de modo universal
terapia gênica.

§ 1º Para uso no SUS, os medicamentos necessários à r
que trata o *caput* deverão estar previamente registrados pela
Vigilância Sanitária (ANVISA).

§2º Uma vez registrada, o portador de Atrofia Muscular
direito de receber, gratuitamente, junto ao SUS, a medica
tratamento.

PROJETO DE LEI Nº , DE 2020
(Do Sr. CELSO MALDANER)

Dispõe sobre a
obrigatória do medica
na lista RENAME e su
Sistema Único de
populares.

O Congresso Nacional decreta:

Art. 1º Fica assegurada a inclusão e a pr
Relação Nacional de Medicamentos Essenciais – RENA
ZOLGENSMA até dezembro de 2020.

Art. 2º O Ministério da Saúde consol
atualizações da RENAME, do respectivo Formulário Te
dos Protocolos Clínicos e Diretrizes Terapêuticas.

Art. 3º Ficam as unidades do programa
Brasil, obrigadas a disponibilizar aos interessados, em lo
listagem medicamentos constantes na Relação Nacion
Essenciais.

Art. 4º Fica o Governo Federal autorizado
medicamento, cuja ausência no âmbito do Sistema Ún
causar riscos à saúde pública.

Art. 5º Esta lei entrará em vigor na data de

APÓS PEDIDO DE VISTA

STF decidirá no plenário físico tese sobre fornecimento de medicamento de alto custo

Ministros já tomaram a decisão no mérito, mas falta fixar uma tese com repercussão geral

KARLA GAMBA

BRASÍLIA

26/08/2021 07:00

JOTA PRO Saúde

Obrigado

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