

Payer coverage and patient access of drugs approved through expedited pathways are not related to pathway status

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OBJECTIVES

The FDA’s Accelerated Approval pathway provides earlier approval of drugs that treat serious conditions and fill an unmet medical need based on a surrogate endpoint. Manufacturers are required to release full trial data after launch. The FDA’s Fast Track pathway facilitates development of drugs that treat serious conditions with unmet need on an expedited timeline, but with full data. We aim to show that payer coverage/non-coverage and patient access of drugs approved through expedited pathways are not related to their pathway status, but rather the strength of their evidence package.

METHODS

We isolated 10 non-oncology, non-infectious rare disease drugs that received Accelerated Approval and 10 that received Fast Track approval. We then analyzed coverage vs. non-coverage across the policies of 10 commercial payers (United Healthcare, Anthem, Aetna, HCBS, BCBS MI, Highmark, Horizon BCBS, Florida Blue, BCBS NC, and Premiera. See references¹⁻¹⁰). We used Chi Square testing to analyze the difference in non-coverage between the groups. We also scored the access policies of these drugs, from least restrictive (3) to most restrictive (0) and analyzed the effect of the pathway on patient access using Chi Square testing.

Drugs Analyzed for Access				
Approval Pathway	Drugs ¹¹	Indication ¹¹	Manufacturer	Year of Approval
Accelerated Approval (AA)	Aduhelm	Alzheimer's disease	Biogen	2021
	Filspari	IgAN	Traverse Tx.	2023
	Galafold	Fabry disease	Amicus Tx.	2018
	Ocaliva	PBC	Intercept Pharm.	2016
	Qalsody	ALS	Ionis Pharm.	2023
	Skysona	CALD	bluebird bio	2022
	Viltepso	DMD	NS Pharma	2020
	Zolgensma	SMA	Novartis	2019
	Zynteglo	B-thalassemia	bluebird bio	2022
Fast Track Approval (FT)	Bylvay	Cholestatic pruritus	Ipsen	2021
	Dojolvi	LC-FAOD	Ultragenyx Pharm.	2020
	Enspryng	NMOSD	Genentech	2020
	Evrysdi	SMA	Genentech	2020
	Lupkynis	Lupus nephritis	Aurinia	2021
	Nexvazyme	Pompe disease	Sanofi Genzyme	2021
	Nucala	Severe asthma	GSK	2020
	Radicava (ors)	ALS	Mitsubishi	2022
	Tepezza	Thyroid eye disease	Horizon Tx.	2020
	Vyvgart	Myasthenia gravis	argenx	2021

Table 1. ALS: Amyotrophic lateral sclerosis; CALD: Cerebral adrenoleukodystrophy; DMD: Duchenne muscular dystrophy; IgAN: Immunoglobulin A nephropathy; LC-FAOD: Long-chain fatty acid oxidation disorders; NMOSD: Neuromyelitis optica spectrum disorder; PBC: Primary biliary cholangitis; Pharm.: Pharmaceuticals; TSMA: Spinal muscular atrophy; Tx.: Therapeutics

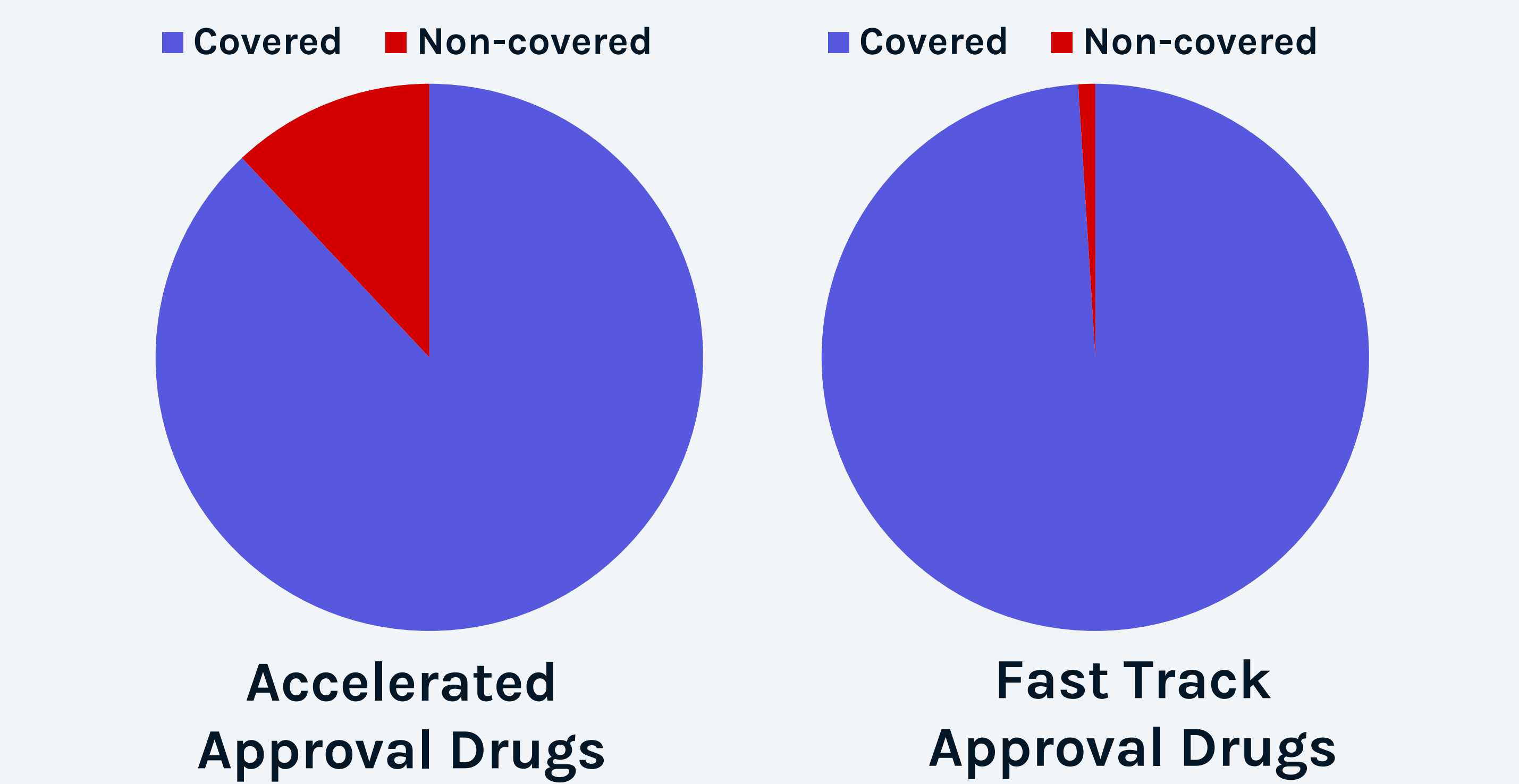
Definitions of Coverage Criteria		
SUBHEADING	Definition	Restriction Level (0-3)
N/A	No coverage criteria found	N/A
Covered	Medication is covered by the payer	N/A
PA to label	Requirements for coverage do not extend beyond the approved indication	3
PA to trial	Requirements for coverage do not extend beyond the inclusion/exclusion criteria in the pivotal trial	2
PA beyond trial	Requirements for coverage extend beyond the inclusion/exclusion criteria in the pivotal trial	1
Not covered	Medication is not covered by the payer; using the medication would mean completely out of pocket costs	0

Table 2. PA: Prior authorization

RESULTS

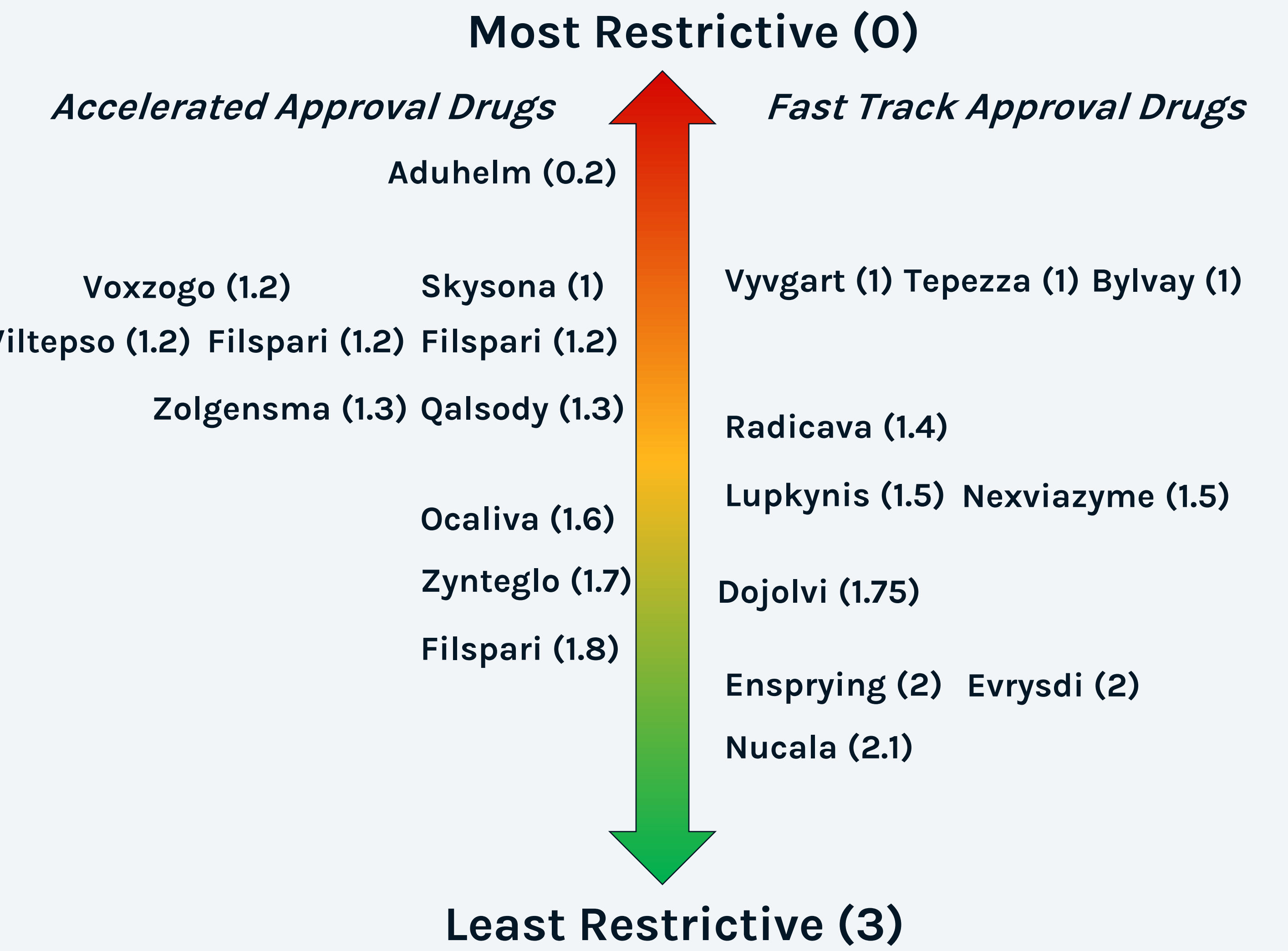
Drugs with Accelerated Approval have significantly more *non-coverage* policies than drugs with Fast Track approval (p < 0.01, df=1). Through our scoring process, payer policies for Accelerated Approval drugs are on average more restrictive on patient access (1.26) than Fast Track drugs (1.51).

Coverage vs. Non-coverage of AA and FT Drugs



n= 10 plans, ~102M covered lives

Payer Restrictions of AA and FT Drugs



AA: Accelerated Approval; FT: Fast Track Approval. Graphic is illustrative.

CONCLUSIONS

Non-oncology, rare disease Accelerated Approval drugs face more non-coverage policies than non-oncology, rare disease Fast Track drugs. By definition, Accelerated Approval drugs launch with incomplete data. Thus, our research demonstrates that the robustness of data packages, independent of an expedited regulatory status, is influential on payer coverage and patient access.

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