

Innovations in Prevention: Implications for Pediatric Patient Access and Public Health

Coverage Pathways Will Determine Overall Patient Out-of-Pocket Costs and Access

Under today's policies, novel "vaccine-like" prophylactic products are likely to be covered and accessed through similar pathways as traditional drugs, posing a range of potential coverage and access barriers, which may expose patients to higher out-of-pocket costs, limiting uptake and public health impact:

Coverage

The same coverage requirements for vaccines do not apply to traditional drugs. Section 2713 of the Public Health Service Act (PHSA) requires non-grandfathered group health plans and issuers in the group and individual markets to cover immunizations for routine use in children and adolescents that have in effect an ACIP recommendation.

Individual Benefit Design

Unlike vaccines, cost sharing for these vaccine-like products will be determined by an individual's health insurance benefit design.

Utilization Management

Payers have also imposed UM techniques for vaccine-like products by implementing policies aligned with professional guidelines rather than the Food & Drug Administration label, limiting coverage to select populations.

90% Average childhood vaccination rate since VFC Implementation

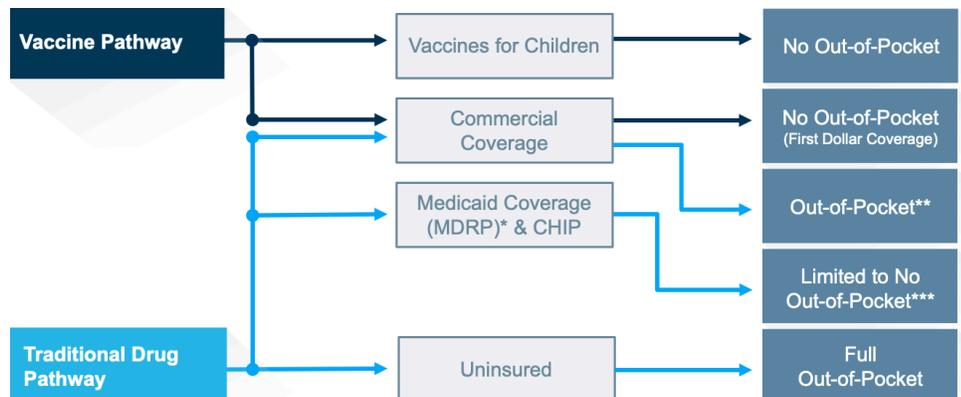
23.6 Average percentage point increase in vaccination rates; 1992-2009

As the pipeline of novel vaccines expands, so does the pipeline for other "vaccine-like" products. Sharing similar characteristics to vaccines, vaccine-like products are intended to, or may be indicated for, the prevention of infectious disease, especially for diseases for which no vaccine is currently available. However, they remain in a "grey zone" between traditional drugs and vaccines, impacting their coverage and access under current US insurance requirements and public health programs. Current vaccine-like products, including monoclonal antibodies (mAb) and immunoglobulins (Ig) administered prophylactically and which are indicated for narrow populations, have not historically been included in traditional vaccine access pathways, such as the Vaccines for Children Program. Given provider and patient impact, the addition of vaccine-like products to such programs may have implications for uptake and public health, especially among pediatric populations.

Differences between Traditional Drug and Vaccines Access Pathways Could Affect Uptake of Vaccine-Like Products

	Function /	Patient Coverage /	Patient Access /	Provider Impact /	Public Health Impact /
Vaccine	Confers immunity	Guaranteed coverage and access without OOP under the ACA and VFC program	No OOP improves access	ACIP recommendations guide timing and setting of provider administration	Increases in vaccine uptake can reduce overall burden of infectious disease and increase public health
Drug	Cures or treats an infectious disease	Coverage varies by plan type; OOP costs vary by plan type	Variable OOP and coverage may result in varied uptake	Professional society guidelines inform provider administration; potential non-coverage could discourage timely administration	Targeted to individual conditions and subject to potential UM; limited public health impact as health benefit realized in individuals

Leveraging Vaccine Access Pathways for Vaccine-Like Products Would Lower Patient Cost Sharing



*Products administered in-patient are not eligible for inclusion in the MDRP

**Individuals will be subject to varying benefit structures

***Per federal statute, Medicaid and Medicaid Expansion CHIP exempts all services for children from cost sharing. CHIP may impose cost sharing up to 20% of the cost for a service, though there is an annual cap based on family income

Stakeholders evaluating the potential public health impact of vaccine-like products may benefit from considering the implications of both pathways for coverage and access. Should vaccine-like products be covered and accessed like traditional drugs, patients may face increased coverage variability, which in turn, could increase health disparities between those who can access such products and those who face access challenges. As the pipeline of vaccine-like products grows, expanding coverage and access policies to accommodate them without patient access barriers, will help facilitate their broad public health impact.