

Vaccine	Manufacturer	BLA submitted to FDA	BLA age indications**	FDA licensure	Status of AAP/CDC recommendations***
DTaP-IPV (KINRIX)	GlaxoSmithKline (GSK)	Jun-2007	4 through 6 years of age	Licensed 24-Jun-08	AAP: aapnews.aappublications.org/cgi/content/full/29/8/20 CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5739a4.htm
DTaP-IPV/Hib (PENTACEL™)	sanofi pasteur	Jul-2005	2, 4, 6, and 15 through 18 months of age	Licensed 20-Jun-08	AAP: aapnews.aappublications.org/cgi/content/full/29/8/1-b CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5739a5.htm
Hib (Hiberix®)	GlaxoSmithKline (GSK)	Mar-2009	Booster dose in children 15 months through 4 years of age	Licensed 19-Aug-09	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5836a5.htm
Hepatitis A (VAQTA®)	Merck	Supplement to original BLA	Greater than or equal to 12 months of age	Licensed 11-Aug-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics:120/1/189 CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5507a1.htm
Hepatitis A (HAVRIX®)	GlaxoSmithKline (GSK)	Supplement to original BLA	Greater than or equal to 12 months of age	Licensed 17-Oct-05	CDC for post-exposure and for international travelers: cdc.gov/mmwr/preview/mmwrhtml/mm5641a3.htm
Hepatitis A and Hepatitis B (TWINRIX®)	GlaxoSmithKline (GSK)	Supplement to original BLA: accelerated dosing	Greater than or equal to 18 years of age: 0, 7, and 21 through 30 days; 12 month booster	Licensed 28-Mar-07	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5640a5.htm
Herpes zoster vaccine (ZOSTAVAX®)	Merck	Apr-2005	Greater than or equal to 60 years of age	Licensed 25-May-06	ACIP: cdc.gov/mmwr/preview/mmwrhtml/rr57e0515a1.htm
HPV4 (GARDASIL®)	Merck	Dec-2005	Females 9 through 26 years of age (3 doses)	Licensed 8-Jun-06	ACIP: cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics:120/3/666
		Supplement to original BLA	Males 9 through 26 years of age	Licensed 16-Oct-09	Pending publication
		Supplement to original BLA	Females 27 through 45 years of age	To be reviewed	Pending FDA licensure
HPV2 (Cervarix™)	GlaxoSmithKline (GSK)	Mar-2007	10 through 25 years of age	Licensed 16-Oct-09	Pending publication
Influenza vaccines - TIV	varies	n/a	See recommendations	varies	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics:124/4/1216 CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5808a1.htm
Influenza -LAIV-T (FluMist®)	MedImmune	Supplement to original BLA	24 months through 49 years of age	Licensed 19-Sep-07	CDC Seasonal: cdc.gov/flu CDC H1N1: cdc.gov/h1n1
Japanese Encephalitis (IXIARO)	InterCell Biomedical	Dec-2007	Greater than or equal to 17 years of age	Licensed 30-Mar-09	ACIP Provisional: cdc.gov/vaccines/recs/provisional/downloads/je-july2009-508.pdf
MCV4 (Menactra®)	sanofi pasteur	Dec-2003	11 through 55 years of age	Licensed 14-Jan-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics:116/2/496 CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm
		Supplement to original BLA	2 through 10 years of age only for children at high risk	Licensed 18-Oct-07	ACIP: cdc.gov/mmwr/preview/mmwrhtml/mm5717a4.htm
MCV4 (Menveo™)	Novartis	Aug-2008	11 through 55 years of age	To be reviewed	Pending FDA licensure
MenCY-Hib (MenHibrix™)	GlaxoSmithKline (GSK)	2009	2, 4, 6 and 12 months of age	To be reviewed	Pending FDA licensure
MMRV (ProQuad®)	Merck	Aug-2004	Same as for MMR dose 1 or dose 2; 12 months to 12 years of age	Licensed 6-Sep-05	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5447a4.htm CDC Update: cdc.gov/vaccines/recs/provisional/downloads/mmr-v-oct2009-508.pdf
PCV13 (Prevnar 13®)	Wyeth	Mar-2009	2 months through 5 years of age	To be reviewed	Pending FDA licensure
Rotavirus (ROTATEQ®)	Merck	Apr-2005	2, 4, and 6 months of age	Licensed 3-Feb-06	
Rotavirus (ROTARIX®)	GlaxoSmithKline (GSK)	Jun-2007	2 and 4 months of age	Licensed 3-Apr-08	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics:123/5/1412 ACIP: cdc.gov/mmwr/PDF/rr/rr5802.pdf
Tdap (BOOSTRIX®)	GlaxoSmithKline (GSK)	Jul-2004	10-18 years of age	Licensed 3-May-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics:117/3/965 CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5503a1.htm
		Supplement to original BLA	19 through 64 years of age	Licensed 4-Dec-08	CDC: cdc.gov/mmwr/preview/mmwrhtml/mm5814a5.htm
Tdap (ADACEL™)	sanofi pasteur	Aug-2004	11 through 64 years of age	Licensed 10-Jun-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics:117/3/965 CDC Adolescent: cdc.gov/mmwr/preview/mmwrhtml/rr5503a1.htm CDC Adult: cdc.gov/mmwr/preview/mmwrhtml/rr5517a1.htm ACIP in Pregnancy: cdc.gov/mmwr/preview/mmwrhtml/rr5704a1.htm
Varicella virus second dose (Varivax®)	Merck	Supplement to original BLA: second dose	12 months to 12 years of age (3 month minimum interval)	Licensed 5-Apr-05	AAP: aappolicy.aappublications.org/cgi/content/full/pediatrics:120/1/221 CDC: cdc.gov/mmwr/preview/mmwrhtml/rr5604a1.htm

Table Updated: 11/4/09

Table available on Red Book Online: www.aapredbook.org/news/vaccstatus.dtl

Vaccine supply shortages may result in changes to recommendations. Please consult cdc.gov/vaccines/vac-gen/shortages/default.htm



BLA = biologics license application, VRBPAC = Vaccines and Related Biological Products Advisory Committee, FDA = Food and Drug Administration, AAP = American Academy of Pediatrics, ACIP = Advisory Committee on Immunization Practices,

DTaP = Diphtheria, Tetanus and Pertussis, Hib = Haemophilus influenzae b, HPV = human papillomavirus vaccine, IPV = Inactivated Poliovirus Vaccine, LAIV-T = Live attenuated influenza vaccine-trivalent,

MCV4 = Meningococcal conjugate vaccine, MMRV = measles, mumps, rubella, varicella, PCV7 = Pneumococcal 7-valent conjugate, Tdap = Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, adsorbed

**Information from vaccine manufacturers, from ACIP meetings and from AAP

**Age licensure can change following FDA review; not final until package insert approved

***ACIP recommendations do not become official until approved by the CDC Director and Department of HHS and publication in MMWR