

Division of Workers' Compensation Pharmacy and Therapeutics Committee

January 15, 2025
12:30pm to 2:30pm



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Gavin Newsom
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Agenda

- **Welcome and Introductions**
George Parisotto, Administrative Director, DWC
- **Physician and Pharmaceutical Fee Schedule Update**
George Parisotto
- **P&T Committee Term and Recruitment**
- **Approval of Minutes from the October 16, 2024 Meeting**
Dr. Raymond Meister, Executive Medical Director, DWC
- **Discussion:**
 - Biosimilars and Generics – *Kevin Gorospe Pharm D, DWC Consultant*
 - Naproxen and Naproxen Sodium – *Kevin Gorospe Pharm D, DWC Consultant*
 - Cannabis Coverage – *Kevin Gorospe Pharm D, DWC Consultant*
- **Additional Public Comments**
- **Review of Committee Recommendations**
- **Adjourn**

Welcome and Introductions

George Parisotto

Administrative Director, DWC

Physician and Pharmaceutical Fee Schedule Update

George Parisotto

Administrative Director, DWC



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Final Regulations Published

- Fee schedule regulations have been finalized
- Implementation of new fee regulations July 1, 2025
- Pharmacy Fee Schedule (PFS) drug pricing data will be made available prior to implementation
 - Website with test data may not be the final website used for access
- Upon implementation, data will be updated on a weekly basis
- Data file formats, data definitions and related links will be available on the PFS data website

P&T Committee Term and Recruitment

George Parisotto

Administrative Director, DWC

Approval of Minutes

Dr. Raymond Meister

Executive Medical Director, DWC

Biosimilars and Generics

J. Kevin Gorospe, PharmD
DWC Consultant



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Biosimilars Different than Generics

- Both are versions of a brand-name drug
- Generics are often referred to as “small molecule” drugs while Biosimilars are larger more complex molecules
- The FDA approval pathway is different between the two
- Both drug approval pathways are considered “abbreviated”, meaning the manufacturer is not required to perform certain clinical trials which reduces the initial cost of a generic or biosimilar

Generic Approval

- Synthesized from chemicals resulting in the same active ingredient as the brand-name product
- Manufacturer of a generic drug must demonstrate the generic is bioequivalent to the brand-name drug
- FDA reviews generics through the Abbreviated New Drug Application (ANDA) process

Biological Listings / Definitions

- All approved biologicals are listed in the FDA Purple Book - <https://purplebooksearch.fda.gov/>
- Reference product - is the single biological product licensed by the FDA under against which a proposed biological product is evaluated (i.e. the original approved biological product)
- Biosimilar - the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components, and there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product
- Interchangeable - biological product is a product that has been shown to be biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient

Biosimilar Approval

- Typically manufactured from living systems
- Due to small variations in production, biosimilars are not exact copies of the reference product
 - This same variation occurs within the reference product
- Manufacturers must demonstrate that the biosimilar is highly similar to the reference product
- Manufacturers must demonstrate there are no meaningful clinical differences between the biosimilar and reference drug in terms of purity, safety, potency
- Biosimilars are approved through the Biological License Application process

Interchangeability

- Generic drugs are considered fully interchangeable with the brand-name drug because they are identical or bioequivalent
- Biosimilars are not considered interchangeable until the FDA provides that designation
- The Biologics Price Competition and Innovation Act of 2009 identifies that a biosimilar can be deemed interchangeable if the information submitted in the application or supplement is sufficient to show
 - that the biological product can be expected to produce the same clinical result as the reference product in any given patient, and
 - that for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch

MTUS Biosimilars Interchangeability

Drug Ingredient	Reference Brand Name
adalimumab	HUMIRA
adalimumab-aacf	IDACIO
adalimumab-aaty	YUFLYMA
adalimumab-adaz	HYRIMOZ (interchangeable)
adalimumab-adbm	CYLTEZO (interchangeable)
adalimumab-afzb	ABRILADA (interchangeable)
adalimumab-aqvh	YUSIMRY
adalimumab-atto	AMJEVITA (interchangeable)
adalimumab-bwwd	HADLIMA (interchangeable)
adalimumab-fkjp	HULIO
adalimumab-ryvk	SIMLANDI (interchangeable)
etanercept	ENBREL
etanercept-szsz	ERELZI
etanercept-ykro	ETICOVO (interchangeable)

California Substitution Statute - Generics

- Business and Professions Code section 4073
- A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients

California Substitution Statute - Biosimilars

- B & P Code section 4073.5
- A pharmacist filling a prescription order for a prescribed biological product may select an alternative biological product only if all of the following:
 - The alternative biological product is interchangeable.
 - The prescriber does not personally indicate “Do not substitute,” or words of similar meaning, in the manner provided in subdivision (d).

Biosimilars Savings

- Association for Accessible Medicines report (compiled by IQVIA) 2023 showed:
 - Biosimilars generated a total of \$23.6 Billion from 2015 -2022
 - Reported that adoption of biosimilars was low, with an average market share of 20% across the treatment areas they were available
 - Average sales price for biosimilars is on average 50% less than the reference brand biologic price was at the time of biosimilar launch
- Report can be found at <https://accessiblemeds.org/resources/reports/2023-savings-report>

Adalimumab Pricing

- Previous pricing presentation did not account for the pricing file using two different units of measure, each syringe versus per milliliter
- Pricing adjusted to reflect per syringe pricing for review
- For all but one strength (10mg/0.1) there are biosimilar drugs that are significantly lower in price than the reference drug HUMIRA

NDC11	LABEL_NAME	GENERIC_NAME	PRICE_AMOUNT
61314050964	HYRIMOZ(CF) 10 MG/0.1 ML SYRINGE	ADALIMUMAB-ADAZ	\$3,288.25
83457081702	CDV HUMIRA(CF) 10 MG/0.1 ML SYR	ADALIMUMAB	\$3,461.31
NDC11	LABEL_NAME	GENERIC_NAME	PRICE_AMOUNT
00597058589	ADALIMUMAB-ADB(M) 10 MG/0.2 ML SYRINGE	ADALIMUMAB-ADB(M)	\$657.65
55513041301	AMJEVITA(CF) 10 MG/0.2 ML SYRINGE	ADALIMUMAB-ATTO	\$3,288.24
00597040089	CYLTEZO(CF) 10 MG/0.2 ML SYRINGE	ADALIMUMAB-ADB(M)	\$3,288.25
NDC11	LABEL_NAME	GENERIC_NAME	PRICE_AMOUNT
83457010801	CDV HYRIMOZ(CF) 20 MG/0.2 ML SYR	ADALIMUMAB-ADAZ	\$650.00
55513039901	AMJEVITA(CF) 20 MG/0.2 ML SYRINGE	ADALIMUMAB-ATTO	\$692.61
72606004101	ADALIMUMAB-AATY(CF) 20 MG/0.2 ML SYRINGE	ADALIMUMAB-AATY	\$1,038.00
61314047664	HYRIMOZ(CF) 20 MG/0.2 ML SYRINGE	ADALIMUMAB-ADAZ	\$3,288.25
00074061602	HUMIRA(CF) 20 MG/0.2 ML SYRINGE	ADALIMUMAB	\$3,368.03
83457061602	CDV HUMIRA(CF) 20 MG/0.2 ML SYR	ADALIMUMAB	\$3,461.31
72606002401	YUFLYMA(CF) 20 MG/0.2 ML SYRINGE	ADALIMUMAB-AATY	\$6,576.50
NDC11	LABEL_NAME	GENERIC_NAME	PRICE_AMOUNT
83257002042	ADALIMUMAB-FKJP(CF) 20 MG/0.4 ML SYRINGE	ADALIMUMAB-FKJP	\$497.50
00025033302	ABRILADA(CF) 20 MG/0.4 ML SYRINGE	ADALIMUMAB-AFZB	\$519.00
00069033302	ABRILADA(CF) 20 MG/0.4 ML SYRINGE	ADALIMUMAB-AFZB	\$3,288.25
83257001642	HULIO(CF) 20 MG/0.4 ML SYRINGE	ADALIMUMAB-FKJP	\$3,288.25
NDC11	LABEL_NAME	GENERIC_NAME	PRICE_AMOUNT
00597055580	ADALIMUMAB-ADB(M) 20 MG/0.4 ML SYRINGE	ADALIMUMAB-ADB(M)	\$657.65
55513041101	AMJEVITA(CF) 20 MG/0.4 ML SYRINGE	ADALIMUMAB-ATTO	\$3,288.24
00597040580	CYLTEZO(CF) 20 MG/0.4 ML SYRINGE	ADALIMUMAB-ADB(M)	\$3,288.25

NDC11	LABEL_NAME	GENERIC NAME	PRICE AMOUNT
78206018701	HADLIMA(CF) PUSHTOUCH 40 MG/0.4 ML	ADALIMUMAB-BWWD	\$503.49
51759040202	SIMLANDI(CF) 40 MG/0.4 ML AUTOINJECTOR	ADALIMUMAB-RYVK	\$519.00
51759040217	SIMLANDI(CF) 40 MG/0.4 ML AUTOINJECTOR	ADALIMUMAB-RYVK	\$519.00
51759041222	SIMLANDI(CF) 40 MG/0.4 ML SYRINGE	ADALIMUMAB-RYVK	\$519.00
72606002209	ADALIMUMAB-AATY(CF) 40 MG/0.4 ML AUTOINJECTOR	ADALIMUMAB-AATY	\$519.00
78206018601	HADLIMA(CF) 40 MG/0.4 ML SYRINGE	ADALIMUMAB-BWWD	\$519.00
61314032720	ADALIMUMAB-ADAZ(CF) PEN 40 MG/0.4 ML	ADALIMUMAB-ADAZ	\$635.98
83457010001	CDV HYRIMOZ(CF) PEN 40 MG/0.4 ML	ADALIMUMAB-ADAZ	\$650.00
83457010101	CDV HYRIMOZ(CF) 40 MG/0.4 ML SYR	ADALIMUMAB-ADAZ	\$650.00
00597056520	ADALIMUMAB-ADB(CF) 40 MG/0.4 ML SYRINGE	ADALIMUMAB-ADB	\$657.65
00597057550	ADALIMUMAB-ADB(CF) PEN 40 MG/0.4 ML	ADALIMUMAB-ADB	\$657.65
61314032764	ADALIMUMAB-ADAZ(CF) 40 MG/0.4 ML SYRINGE	ADALIMUMAB-ADAZ	\$657.65
55513047901	AMJEVITA(CF) 40 MG/0.4 ML SYRING	ADALIMUMAB-ATTO	\$692.61
55513047902	AMJEVITA(CF) 40 MG/0.4 ML SYRING	ADALIMUMAB-ATTO	\$692.61
55513048201	AMJEVITA(CF) 40 MG/0.4 ML AUTOINJECTOR	ADALIMUMAB-ATTO	\$692.61
55513048202	AMJEVITA(CF) 40 MG/0.4 ML AUTOINJECTOR	ADALIMUMAB-ATTO	\$692.61
72606002206	ADALIMUMAB-AATY(CF) 40 MG/0.4 ML SYRINGE	ADALIMUMAB-AATY	\$1,038.00
72606002210	ADALIMUMAB-AATY(CF) 40 MG/0.4 ML AUTOINJECTOR (2 PACK)	ADALIMUMAB-AATY	\$1,038.00
82009014422	ADALIMUMAB-ADB(CF) PEN 40 MG/0.4 ML	ADALIMUMAB-ADB	\$1,875.00
82009014622	ADALIMUMAB-ADB(CF) 40 MG/0.4 ML SYRINGE	ADALIMUMAB-ADB	\$1,875.00
82009015622	ADALIMUMAB-RYVK(CF) 40 MG/0.4 ML AUTOINJECTOR	ADALIMUMAB-RYVK	\$1,875.00
82009015822	ADALIMUMAB-RYVK(CF) 40 MG/0.4 ML SYRINGE	ADALIMUMAB-RYVK	\$1,875.00
00597048520	CYLTEZO(CF) 40 MG/0.4 ML SYRNG	ADALIMUMAB-ADB	\$3,288.25
00597049550	CYLTEZO(CF) PEN 40 MG/0.4 ML	ADALIMUMAB-ADB	\$3,288.25
61314047320	HYRIMOZ(CF) PEN 40 MG/0.4 ML	ADALIMUMAB-ADAZ	\$3,288.25
61314047364	HYRIMOZ(CF) 40 MG/0.4 ML SYRINGE	ADALIMUMAB-ADAZ	\$3,288.25
72606003006	YUFLYMA(CF) 40 MG/0.4 ML SYRINGE	ADALIMUMAB-AATY	\$3,288.25
72606003009	YUFLYMA(CF) 40 MG/0.4 ML AUTOINJECTOR	ADALIMUMAB-AATY	\$3,288.25
72606003010	YUFLYMA(CF) 40 MG/0.4 ML AUTOINJECTOR (2 PACK)	ADALIMUMAB-AATY	\$3,288.25
00074024302	HUMIRA(CF) 40 MG/0.4 ML SYRINGE	ADALIMUMAB	\$3,361.37
00074055402	HUMIRA(CF) PEN 40 MG/0.4 ML	ADALIMUMAB	\$3,362.48
83457024302	CDV HUMIRA(CF) 40 MG/0.4 ML SYR	ADALIMUMAB	\$3,461.31
83457055402	CDV HUMIRA(CF) PEN 40 MG/0.4 ML	ADALIMUMAB	\$3,461.31

NDC11	LABEL_NAME	GENERIC_NAME	PRICE_AMOUNT
70114022002	YUSIMRY(CF) 40 MG/0.8 ML PEN	ADALIMUMAB-AQVH	\$497.50
83257002142	ADALIMUMAB-FKJP(CF) 40 MG/0.8 ML SYRINGE	ADALIMUMAB-FKJP	\$497.50
83257002232	ADALIMUMAB-FKJP(CF) PEN 40 MG/0.8 ML	ADALIMUMAB-FKJP	\$497.50
00025032501	ABRILADA(CF) PEN 40 MG/0.8 ML	ADALIMUMAB-AFZB	\$519.00
00025032802	ABRILADA(CF) 40 MG/0.8 ML SYRINGE	ADALIMUMAB-AFZB	\$519.00
78206018301	HADLIMA 40 MG/0.8 ML SYRINGE	ADALIMUMAB-BWWD	\$519.00
78206018401	HADLIMA PUSH TOUCH 40 MG/0.8 ML	ADALIMUMAB-BWWD	\$519.00
83457010201	CDV HYRIMOZ PEN 40 MG/0.8 ML	ADALIMUMAB-ADAZ	\$650.00
83457010301	CDV HYRIMOZ 40 MG/0.8 ML SYR	ADALIMUMAB-ADAZ	\$650.00
00597054522	ADALIMUMAB-ADB(M) (CF) PEN 40 MG/0.8 ML	ADALIMUMAB-ADB(M)	\$657.65
00597059520	ADALIMUMAB-ADB(M) (CF) 40 MG/0.8 ML SYRINGE	ADALIMUMAB-ADB(M)	\$657.65
65219061299	ADALIMUMAB-AAC(F) (CF) PEN 40 MG/0.8 ML	ADALIMUMAB-AAC(F)	\$899.00
65219062020	ADALIMUMAB-AAC(F) (CF) 40 MG/0.8 ML SYRINGE	ADALIMUMAB-AAC(F)	\$899.00
00025032502	ABRILADA(CF) PEN 40 MG/0.8 ML	ADALIMUMAB-AFZB	\$1,038.00
72511040001	AMJEVITA(CF) 40 MG/0.8 ML AUTOINJECTOR	ADALIMUMAB-ATTO	\$1,557.59
72511040002	AMJEVITA(CF) 40 MG/0.8 ML AUTOINJECTOR	ADALIMUMAB-ATTO	\$1,557.59
82009014822	ADALIMUMAB-ADB(M) (CF) PEN 40 MG/0.8 ML	ADALIMUMAB-ADB(M)	\$1,875.00
82009015022	ADALIMUMAB-ADB(M) (CF) 40 MG/0.8 ML SYRINGE	ADALIMUMAB-ADB(M)	\$1,875.00
55513040001	AMJEVITA(CF) 40 MG/0.8 ML AUTOINJECTOR	ADALIMUMAB-ATTO	\$3,288.24
55513040002	AMJEVITA(CF) 40 MG/0.8 ML AUTOINJECTOR	ADALIMUMAB-ATTO	\$3,288.24
55513041001	AMJEVITA(CF) 40 MG/0.8 ML SYRINGE	ADALIMUMAB-ATTO	\$3,288.24
00069032502	ABRILADA(CF) PEN 40 MG/0.8 ML	ADALIMUMAB-AFZB	\$3,288.25
00069032802	ABRILADA(CF) 40 MG/0.8 ML SYRINGE	ADALIMUMAB-AFZB	\$3,288.25
00597037082	CYLTEZO(CF) 40 MG/0.8 ML SYRINGE	ADALIMUMAB-ADB(M)	\$3,288.25
00597037597	CYLTEZO(CF) PEN 40 MG/0.8 ML	ADALIMUMAB-ADB(M)	\$3,288.25
83257001742	HULIO(CF) 40 MG/0.8 ML SYRINGE	ADALIMUMAB-FKJP	\$3,288.25
83257001932	HULIO(CF) PEN 40 MG/0.8 ML	ADALIMUMAB-FKJP	\$3,288.25
00069032501	ABRILADA(CF) PEN 40 MG/0.8 ML	ADALIMUMAB-AFZB	\$3,288.25
00074379902	HUMIRA 40 MG/0.8 ML SYRINGE	ADALIMUMAB	\$3,361.47
00074433902	HUMIRA PEN 40 MG/0.8 ML	ADALIMUMAB	\$3,364.95
65219055408	IDACIO(CF) PEN 40 MG/0.8 ML	ADALIMUMAB-AAC(F)	\$6,576.49
65219055618	IDACIO(CF) 40 MG/0.8 ML SYRINGE	ADALIMUMAB-AAC(F)	\$6,576.49

NDC11	LABEL_NAME	GENERIC_NAME	PRICE_AMOUNT
72606004004	ADALIMUMAB-AATY(CF) 80 MG/0.8 ML AUTOINJECTOR	ADALIMUMAB-AATY	\$519.00
83457010701	CDV HYRIMOZ(CF) PEN 80 MG/0.8 ML	ADALIMUMAB-ADAZ	\$1,300.00
55513048101	AMJEVITA(CF) 80 MG/0.8 ML AUTOINJECTOR	ADALIMUMAB-ATTO	\$1,385.22
55513048102	AMJEVITA(CF) 80 MG/0.8 ML AUTOINJECTOR	ADALIMUMAB-ATTO	\$1,385.22
72606002304	YUFLYMA(CF) 80 MG/0.8 ML AUTOINJECTOR	ADALIMUMAB-AATY	\$3,288.25
61314045420	HYRIMOZ(CF) PEN 80 MG/0.8 ML	ADALIMUMAB-ADAZ	\$6,576.51
00074012402	HUMIRA(CF) PEN 80 MG/0.8 ML	ADALIMUMAB	\$6,726.58
83457012402	CDV HUMIRA(CF) PEN 80 MG/0.8 ML	ADALIMUMAB	\$6,922.64

Committee Discussion

Public Comments

Naproxen and Naproxen Sodium

J. Kevin Gorospe, PharmD
DWC Consultant



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Naproxen Differences

- Primary difference between Naproxen and Naproxen Sodium is absorption rate
 - Naproxen Sodium reaches peak plasma concentration after 1 hour
 - Naproxen reaches peak plasma concentration after 2 hours
 - Enteric coated and controlled release formulations of Naproxen take longer to hit peak concentration
 - The pharmacokinetics after reaching peak are the same for both
- Earlier peak make naproxen sodium better for acute pain
- Naproxen dose equivalents

NAPROXEN	NAPROXEN SODIUM
200 MG	220 MG
250 MG	275 MG
500 MG	500 MG

Naproxen Pricing

- Spreadsheets showing most recent Medi-Cal based pricing
- Generic drug pricing based on WAC or Generic NADAC
- Brand drug pricing based on WAC or Brand NADAC
 - WAC is Wholesale Acquisition Cost as reported by manufacturer
 - NADAC is the National Average Drug Acquisition Cost as reported by the Centers for Medicare and Medicaid Services (CMS) for use by states
- Tables are broken out by strength for comparative purposes as well as a column showing the price to reach a 500mg dose
- Repackaged products (products typically repackaged for physician dispensing) are also identified
- 220 MG products are Over-the-counter; all others are prescription only

Committee Discussion

Public Comments

Cannabis Coverage

J. Kevin Gorospe, PharmD
DWC Consultant



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Cannabis

- Currently a Schedule 1 (illegal) drug
- The federal Department of Justice has proposed moving cannabis to Schedule 3 (proposed rule at <https://www.federalregister.gov/documents/2024/05/21/2024-11137/schedules-of-controlled-substances-rescheduling-of-marijuana>)
- Schedule 3 drugs are defined as drugs with a moderate to low potential for physical and psychological dependence and an abuse potential is less than Schedule I and Schedule II drugs

Coverage Under Workers Compensation

- Medical marijuana may be covered as a treatment under California workers compensation.
 - MTUS Guidance
 - ACOEM Update

Committee Discussion

Public Comments

Review of Recommendations

Adjournment