

**REPORT/RECOMMENDATION TO THE BOARD OF SUPERVISORS
OF THE COUNTY OF SAN BERNARDINO
AND RECORD OF ACTION**

May 4, 2021

FROM

WILLIAM L. GILBERT, Director, Arrowhead Regional Medical

SUBJECT

Free Trial Programs for Invega Sustenna and Aristada Medications

RECOMMENDATION(S)

1. Authorize the Arrowhead Regional Medical Center Director of Pharmacy to electronically execute and transmit an application, subject to review by County Counsel, to register free of charge with the Invega Sustenna Inpatient Hospital Free Trial Program offered by Janssen Pharmaceuticals, for Invega Sustenna.
2. Authorize the Arrowhead Regional Medical Center Director of Pharmacy to electronically execute and transmit an application, subject to review by County Counsel, to register free of charge with the Aristada Free Inpatient Trial Program offered by Alkermes, for Aristada.
(Presenter: William L. Gilbert, Director, 580-6150)

COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES

Provide for the Safety, Health and Social Service Needs of County Residents.

Operate in a Fiscally Responsible and Business-Like Manner

FINANCIAL IMPACT

Approval of this item will not result in the use of Discretionary General Funding (Net County Cost) as there is no cost to register with the trial programs.

BACKGROUND INFORMATION

Approval of Recommendation No. 1 will allow for the participation of Arrowhead Regional Medical Center (ARMC) in the Invega Sustenna Inpatient Hospital Free Trial Program. As a participant, the hospital will receive the starting dose of the Invega Sustenna medication, a long acting antipsychotic form of paliperidone palmitate. Janssen Pharmaceuticals offers up to two free trial units per calendar year per patient, at no charge for inpatient hospital and crisis stabilization unit pharmacies in hospitals that are validly licensed under applicable state law for treatment of appropriate inpatient behavioral health patients. Additionally quantity limits for the program are up to 96 units per prescriber and no more than 480 units per hospital, each within a six month period. It has been reported that readmissions of patients with schizophrenia are generally due to noncompliance with medications. Long-acting antipsychotic agents, such as the Invega Sustenna medication, may reduce outpatient medication compliance problems by eliminating the need for daily oral medications as the long-acting medication is administered only once per month.

Approval of Recommendation No. 2 will allow for the participation of ARMC in the Alkermes Hospital Inpatient Free Trial Program to receive free of charge up to two free trial units per

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patient per calendar year of Aristada, a long acting antipsychotic form of aripiprazole, for appropriate inpatient behavioral health patients. As with the Invega Sustenna medication, long-acting antipsychotic agents may reduce outpatient medication compliance problems by eliminating the need for daily oral medications. As a result, inpatient hospital admissions may be avoided due to improved medication compliance.

Neither the patients nor their payors (if applicable) will be charged for the trial units of the medications that are administered to the patients. There is no obligation to continue to use or purchase either of the medications after the administration of the trial units.

Registration of the two programs requires a pharmacist with authority to bind the County to agree to certain rules of the programs pertaining to tracking of utilization of the trial units and not charging patients or their payors for the medications, as more fully set forth in Attachments A and B. Additionally, the terms of the program lack the standard County contract terms discussed below. As a result, ARMC is requesting authority from the Board to authorize the ARMC Director of Pharmacy to submit the applications to register for the programs.

Insurance

The program terms do not require Janssen Pharmaceuticals or Alkermes (collectively, "Pharmaceutical Companies") to meet the County insurance standards.

- The County standard contract requires contractors to carry appropriate insurance at limits and under conditions determined by the County Risk Management Department.
- Potential Impact: The program terms do not include County standard insurance requirements. This means that the County has no assurance of an insurance company that the Pharmaceutical Companies will be financially responsible for claims that may arise from the programs, which may result in expenses to the County.

Indemnification

The Pharmaceutical Companies are not contractually obligated to defend, indemnify, or hold the County harmless for any claims, including for intellectual property infringement claims.

- The standard contract provision for intellectual property indemnity is: Contractor will indemnify, defend, and hold harmless County and its officers, employees, agents and volunteers, from any and all third party claims, costs (including without limitation reasonable attorneys' fees), and losses for infringement of any United States patent, copyright, trademark or trade secret (Intellectual Property Rights) by any goods or services. The County standard contract general indemnity provision requires the Contractor to indemnify, defend, and hold County harmless from third party claims arising out of the acts, errors or omissions of any person.
- Potential Impact: The Pharmaceutical Companies are not contractually required to defend, indemnify or hold the County harmless from any claims, including indemnification for claims arising from their negligent or intentional acts and intellectual property infringement. If the County is sued for any claim, including intellectual property infringement based on its use of the Pharmaceutical Companies' medication, the County may be solely liable for the costs of defense and damages, which could exceed the total contract amount.

Governing Law and Venue

There is no governing law or venue stated in the program terms.

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- The County standard contract requires governing law to be California and the venue for disputes to be the Superior Court of California, County of San Bernardino, San Bernardino District.
- Potential Impact: Having no express provision relating to governing law or venue creates an ambiguity as to which state's law applies to the program terms. Having no express venue in the terms means that the venue could be in a different county or state, which may require the County to retain outside counsel, resulting in expenses to the County.

ARMC recommends approval of this delegation of authority to enable the hospital to provide for the safety, health and social service needs of County residents by providing access to medications that may be more effective in the treatment of behavioral health patients at the hospital at no cost to the hospital or its patients.

PROCUREMENT

Not applicable.

REVIEW BY OTHERS

This item has been reviewed by County Counsel (Charles Phan, Deputy County Counsel, 387-5455) on April 7, 2021; ARMC Finance (Chen Wu, Budget and Finance Officer, 580-3165) on April 12, 2021; Finance (Yael Verduzco, Administrative Analyst, 387-5285) on April 14, 2021; and County Finance and Administration (Matthew Erickson, County Chief Financial Officer, 387-5423) on April 18, 2021.

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Record of Action of the Board of Supervisors
County of San Bernardino

APPROVED (CONSENT CALENDAR)

Moved: Joe Baca, Jr. Seconded: Col. Paul Cook (Ret.)

Ayes: Col. Paul Cook (Ret.), Janice Rutherford, Dawn Rowe, Curt Hagman, Joe Baca, Jr.

Lynna Monell, CLERK OF THE BOARD

BY 
DATED: May 4, 2021



cc: File- Medical Center w/attach
LA 05/7/2021