

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

June 28, 2022

FROM

WILLIAM L. GILBERT, Director, Arrowhead Regional Medical Center

SUBJECT

Annual Re-Enrollment for Free Trial Programs Providing Invega Sustenna and Aristada Medications

RECOMMENDATION(S)

1. Authorize the Arrowhead Regional Medical Center Director of Pharmacy to electronically execute and transmit annual re-enrollment applications, subject to review by County Counsel, to register free of charge with the Invega Sustenna Hospital Free Trial Program offered by Janssen Pharmaceuticals.
2. Authorize the Arrowhead Regional Medical Center Director of Pharmacy to electronically execute and transmit annual re-enrollment applications, subject to review by County Counsel, to register free of charge with the Aristada Free Inpatient Trial Program by Alkermes.

(Presenter: William L. Gilbert, Director, 580-6150)

COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES

Operate in a Fiscally-Responsible and Business-Like Manner.

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

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 and re-enroll with the trial programs at this time.

BACKGROUND INFORMATION

Approval of the annual re-enrollment applications will allow Arrowhead Regional Medical Center ("ARMC") to continue to receive specific, long acting antipsychotic medications for the treatment of behavioral health patients at no cost to the County.

As a participant in the program offered by Janssen Pharmaceuticals, ARMC will continue to 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.

The continued participation of ARMC in the Alkermes Program will allow the hospital to continue to receive up to two free trial units per patient per calendar year of Aristada, a long acting antipsychotic form of aripiprazole, for appropriate inpatient behavioral health patients. The free

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trial will continue until terminated by the vendor or the County discontinues enrollment, which is completed annually.

On May 4, 2021 (Item No. 12), the Board of Supervisors (Board) authorized the ARMC Director of Pharmacy to electronically execute and transmit an application, subject to review by County Counsel, to register free of charge with Invega Sustenna Inpatient Hospital Free Trial Program offered by Janssen Pharmaceuticals, as well as the Aristada Free Inpatient Trial Program offered by Alkermes for the one-year initial trial.

Initial registration as well as annual re-enrollments for the two programs requires a licensed 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 contain non-standard terms, as discussed below:

1. The program terms do not require Janssen Pharmaceuticals or Alkermes (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 that the Pharmaceutical Companies will maintain insurance coverage for claims that may arise from the programs, which may result in expenses to the County.
2. The Pharmaceutical Companies are not contractually obligated to defend, indemnify, or hold the County harmless for any claims, including 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.
3. There is no governing law or venue stated in the program terms.
 - 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

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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 the delegation of authority for the submission of the annual re-enrollment applications, to provide for the health and safety 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 patients.

PROCUREMENT

Not applicable.

REVIEW BY OTHERS

This item has been reviewed by County Counsel (Charles Phan, Deputy County Counsel, 387-5455) on May 23, 2022; ARMC Finance (Chen Wu, Finance and Budget Officer, 580-3165) on June 2, 2022; Finance (Jenny Yang, Administrative Analyst, 387-4884) on June 2, 2022; and County Finance and Administration (Diana Atkeson, Deputy Executive Officer, 387-5423) on June 2, 2022.

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Record of Action of the Board of Supervisors
San Bernardino County

APPROVED (CONSENT CALENDAR)

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

Lynna Monell, CLERK OF THE BOARD

BY

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DATED: June 28, 2022



cc: File - Medical Center w/attach
CCM 07/13/2022