Need help?
Call 1-844-350-9656
Fax: 1-513-506-7361
Hours: Mon-Fri, 9:00AM-6:00PM ET

Palette Life Sciences, Inc.
Temporary Rebate Initiative for Solesta®

Palette Life Sciences is pleased to offer a new Temporary Rebate Initiative (TRI) for Solesta.
The TRI is intended to address concerns about reimbursement challenges previously faced when using Solesta® and to ensure that patients have access to this therapy while payers establish clearer policies for coverage and reimbursement.

The key elements of this temporary initiative are:

1. Participant will enter a Solesta Temporary Rebate Initiative Agreement with Palette

2. Participant will purchase the product for full price, administer to patient, and bill the payer per normal practices
   - Participant invoice for product purchase to provide 120-day payment terms – providing time for payer coverage determination & appeal (if needed)

3. Palette will credit participant for the difference between the product purchase price and the reimbursement amount, ***if participant:***
   - Enters into written TRI agreement & complies w/ terms
   - Uses the product on-label
   - Experiences a full denial of coverage or payment that is less than the cost paid for Solesta
   - Cooperates with at least one claims submission appeal
   - Complies with anti-inducement regulations and waives patient fee collections for the product and administration (may collect for insurance copayment and deductible due)
   - Submits completed Temporary Rebate Initiative "Rebate Request Form" with required documentation to Palette

Health Care Providers (HCPs) and Health Care Organizations (HCOs) interested in receiving further information regarding program enrollment, eligibility, and requirements should contact Palette's TRI directly via the information below.

Palette Life Sciences Temporary Rebate Initiative
1-844-350-9656

See the Solesta Temporary Rebate Initiative Agreement for full terms and conditions.

I. ATTACHMENT A

Product Sales & Rebate Agreement

This Purchase Agreement ("AGREEMENT") is entered into between Palette Life Sciences, Inc. ("COMPANY") and _____("CUSTOMER") (the "PARTIES") and is effective the date the PARTIES execute it (the "EFFECTIVE DATE").

1. PURCHASE. COMPANY agrees to provide to CUSTOMER with Solesta (the "PRODUCT"), at the pricing described below. Pricing is firm for a period of twelve (12) months from the EFFECTIVE DATE of the AGREEMENT, and may be subject to adjustment after that period as agreed to by the PARTIES and as reflected in amendments to this AGREEMENT. All prices are for goods delivered F.O.B. point of origin to CUSTOMER's specified destination, freight prepaid and added to invoice. Payment is due 120 days after delivery.

2. PRICING. The pricing for products provided herein may reflect or be subject to discounts, rebates or other price reductions, which customer may be obligated under federal law to report to Medicare, Medicaid or other state, federal or private payers, and to make this information available to these entities for review.

3. TEMPORARY REBATE INITIATIVE. CUSTOMER and COMPANY agree that the PRODUCT is a novel technology, and payer coverage and reimbursement levels may vary. If a claim for the PRODUCT has been submitted and denied by a payer, either in full or in part, after exhausting the appeals process, CUSTOMER will qualify for a special discount in the form of a rebate for up to the PRODUCT's true acquisition cost. This Temporary Rebate Initiative is effective until December 31, 2022. At no time will any credit(s) provided by COMPANY under these INITIATIVES exceed the total actual acquisition cost for individual PRODUCT purchased. In order to participate in the Temporary Rebate Initiative, CUSTOMER must agree to the terms and conditions as defined in the Temporary Rebate Initiative Agreement.

4. TERM AND TERMINATION. The term shall be from the EFFECTIVE DATE until December 31, 2022, unless terminated earlier. Either PARTY may terminate this AGREEMENT upon thirty (30) days prior written notice to the other PARTY.

5. COMPLIANCE WITH LAW. Each PARTY represents and warrants that it shall comply with all applicable federal and state laws and regulations, including, without limitation, the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, any applicable "exceptions" or "safe harbors" under the Federal Anti-Kickback Statute with respect to the AGREEMENT, and any state laws comparable to the Federal Anti-Kickback Statute. In particular, both PARTIES expressly acknowledge that the Federal Anti-Kickback Statute, prohibits "illegal remuneration" as defined therein, in connection with the provision of goods or services for which payment is made in whole or in part under Medicare. It is the intention of the PARTIES hereto that this AGREEMENT shall in all respects comply with the Discount Safe Harbor, 42 C.F.R. § 1001.952(h) or the Statutory Discount Exception, 42 U.S.C. § 1320a-7b(b)(3)(A). CUSTOMER agrees that, if CUSTOMER is required to report its costs on a cost report, then (i) any discounts provided must be based on purchases of the same good bought within a fiscal year; (ii) CUSTOMER must claim the benefit in the fiscal year in which the discount (e.g., rebates are considered discounts) is earned or in the following year; and (iii) CUSTOMER must fully and accurately report any discounts in applicable cost reports. Furthermore, CUSTOMER

represents and warrants that it has independently determined that the PRODUCT is in the best interest of CUSTOMER's patients.

6. CONFIDENTIAL INFORMATION. All information provided to CUSTOMER hereunder, and in particular, information specific to this AGREEMENT and relating to pricing of the PRODUCT shall be deemed "CONFIDENTIAL INFORMATION." Subject to its disclosure obligations described under Paragraph 7 of this AGREEMENT, CUSTOMER agrees not to disclose such CONFIDENTIAL INFORMATION to any third party, or to use such information for any other purpose. This obligation shall continue during the term of this AGREEMENT and for a period of three (3) years following termination or expiration of this AGREEMENT. CONFIDENTIAL INFORMATION shall not be deemed confidential if: (i) it is or becomes public knowledge through no fault of CUSTOMER, or (ii) it is required to be disclosed by law, provided that CUSTOMER shall give maximum practical advance notice of same and request such confidential treatment of such disclosure from the recipient as may be afforded by law. Further, COMPANY represents that it is not a Business Associate as defined in the Health Insurance Portability and Accountability Act ("HIPAA"). The functions COMPANY is required to perform hereunder, e.g., providing guidance on the safe use of COMPANY's products, do not require the use or disclosure of Protected Health Information ("PHI"). To the extent any disclosure of PHI does occur, it is incidental and covered under the incidental disclosure rule found in 45 CFR § 164.502(a)(1).

7. LIMITED WARRANTY. COMPANY WARRANTS THAT THE PRODUCT TO BE SUPPLIED UNDER THIS AGREEMENT IS FIT FOR THE PURPOSE INTENDED WHEN USED AS INTENDED AND AS DIRECTED IN THE PRODUCT INSTRUCTIONS FOR USE. COMPANY DOES NOT WARRANT OR GUARANTEE ANY OUTCOME. NO OTHER EXPRESS OR IMPLIED WARRANTIES ARE GIVEN TO CUSTOMER, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

8. LIMITATION OF LIABILITY. CUSTOMER'S SOLE AND EXCLUSIVE REMEDY FOR A BREACH OF WARRANTY HEREUNDER IS TO HAVE COMPANY PROMPTLY REPLACE ANY PRODUCT. CUSTOMER SHALL HAVE NO OTHER REMEDIES UNDER THIS AGREEMENT.

9. INDEMNITY. COMPANY agrees to indemnify, defend and hold CUSTOMER harmless from any liability, loss, expense, cost, claim or judgment arising out of any claim for property damage, or personal injury or death where the PRODUCT is alleged to have caused or contributed to the damage, injury or death, provided that this indemnification does not extend to injuries, damages or death to the extent caused by the negligence, reckless disregard or intentional acts of CUSTOMER or any third party.

10. ENTIRE AGREEMENT AND WAIVER. This AGREEMENT constitutes the entire AGREEMENT between COMPANY and CUSTOMER with respect to its subject matter and supersedes and replaces all prior and contemporaneous understandings and agreements, oral or written, between COMPANY and CUSTOMER. The terms and conditions of this AGREEMENT may not be waived, modified or amended in any way by conduct, custom or course of dealing; instead, they may be waived only by a written document signed by both PARTIES. The waiver by a PARTY of any term or condition of this AGREEMENT shall not be deemed to be a waiver of any subsequent breach by the other PARTY of the same term or condition or any other term or condition of this AGREEMENT.

11. GOVERNING LAW. This AGREEMENT shall be governed by and construed in accordance with the Laws of the State of Delaware.

12. ASSIGNMENT. Neither PARTY may assign this AGREEMENT without the express written consent of the other PARTY.

By signing below, CUSTOMER and COMPANY agree to be bound by all the terms and conditions contained in this AGREEMENT. Call EVERSANA at (844) 350-9656 if you have any questions.

COMPANY

Signature: 
Printed Name: James Leech
Title: Head of Strategy & Corporate Development
Date: November 19, 2020

CUSTOMER

Signature:_____
Printed Name: _____
Title: _____
Date: _____

II. ATTACHMENT B

Temporary Rebate Initiative Agreement

This Agreement is made on_____/_____/_____("Effective Date"), between, Palette Life Sciences, Inc. ("Palette") and _____, ("Participant"), with offices at _____, collectively, the "Parties." The Parties voluntarily agree to the following Temporary Rebate Initiative ("Initiative") terms and conditions:

1. The intent of the Initiative is only to mitigate the reimbursement risk to facilitate patient access to Solesta, not to cover the cost of patient care, office overhead expenses, physician fees, or to compensate physicians for using Solesta ("Product"). Palette will provide a rebate to make the Participant whole for the Participant's acquisition cost of the Product only. Palette will not provide a rebate to cover any portion of the physician fees for their time and/or services.

2. Participant acknowledges and understands that the Initiative only applies to the FDA approved use of Product by the health care professional signing this agreement and at the above listed physician practice location(s). The current FDA cleared/approved intended use is: *Solesta® is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (e.g., diet, fiber therapy, anti-motility medications).*

3. Participant acknowledges and understands that the Initiative is available to all patients with medical insurance coverage. Uninsured patients are not eligible for the Initiative.

4. Participant acknowledges and agrees not to bill the patient for physician fees related to the Solesta procedure, including all fees for the Participant's time, services, overhead, supplies, and other administrative fees associated with the Solesta procedure under this Initiative. Participant may bill the insurance company for physician fees, e.g., for time and services; however, for the purposes of determining invoice credit eligibility and amount, the amount of reimbursement received for Solesta by an insurance company will be first applied to the acquisition cost of the Product. The invoice credit will not cover any portion of physician fees.

5. Participant attests to having a patient's signed authorization to release information on file in accordance with the Health Insurance Portability and Accountability Act ("HIPAA") to allow for patient eligibility.

6. Participant agrees to submit at least one appeal to the payer.

7. Participant agrees to release or make available to an authorized Initiative Representative the medical records, medical insurance information, or other relevant information (e.g., letter of medical necessity) for eligible patients, within a reasonable time period (e.g., within 3 days of request), for the sole purpose of verifying coverage, obtaining insurance verification, or submitting claim appeals.

8. Participant agrees to communicate on a regular basis, the status of claim payment or denial for all patients enrolled in the Initiative. Such communication will serve as documentation necessary to facilitate invoice credit eligibility as appropriate.

9. Participant agrees to immediately notify the Initiative if they become aware of any changes in the patient's medical insurance coverage or any changes in the payer's coverage policies that could affect the potential coverage of the Product.

10. Participant practice agrees to delay the purchase of Product for patients enrolled in the Initiative until the Initiative has obtained a decision from the payer if preauthorization for coverage is required, and the Initiative authorizes the practice to purchase Product for each patient enrolled.

11. Participant practice agrees to purchase Product for each eligible patient with 120-day payment terms.

12. Participant practice acknowledges an invoice credit may be requested only when:

    a. A claim for Product has been submitted and denied by the insurance company (either in full or in part);
    b. The amount paid by the insurance company (if any) does not cover the Participant's acquisition cost for the Product;
    c. Participant provides all insurance company denial and payment documentation to the Initiative within 30 days of receipt; and
    d. Reasonable efforts to appeal that claim have been pursued during the allotted time period since the purchase of the Product.

13. In the event of eligibility for an invoice credit, Participant must sign and return a Request for Product Invoice Credit form, confirming that any active appeal or claim for the Product has been or will be withdrawn from the insurance company. If an invoice credit is provided, Participant agrees to return to the patient, collected deductible and co-payments for the cost of the Product, in part or in full, as appropriate. Once an invoice credit is provided, Participant agrees not to attempt to continue to seek reimbursement for the Product from any payer or patient.

14. Participant acknowledges that invoice credit eligibility under this Initiative is limited to the purchase price of the Product only and does not cover physician fees for their time or services or any other costs incurred by the Participant.

15. Each Party represents and warrants that it shall comply with all applicable federal and state laws and regulations, including, without limitation, the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), any applicable "exceptions" or "safe harbors" under the Federal Anti-Kickback Statute with respect to the Initiative, and any state laws comparable to the Federal Anti-Kickback Statute. In particular, Participant agrees that any invoice credits received under the Initiative shall be fully and accurately reported as discounts in accordance with all applicable laws and regulations, including the Federal Anti-Kickback Statute and its Discount Safe Harbor regulation, 42 C.F.R. § 1001.952(h) and state law analogs. Participant further agrees to provide all required information pertaining to any invoice credits, upon request, to any state and federal healthcare officials, in accordance with all applicable laws, rules, and regulations.

16. Participant understands that any product purchased under the terms of the agreement which is unused is not returnable for any reason.

17. Participant understands that the Initiative does not promise or guarantee coverage, payment, or rate of payment for the Product or for professional services associated with the use of the Product or any other services or line items billed in conjunction with the use of Product, and hereby acknowledges that participant accepts full risk for reimbursement pertaining to the procedure associated with use of Product and all other services and items other than the Product for each enrolled patient.

18. Participant accepts responsibility for communication and collection of patient financial responsibility for the Product and for related procedural services covered by the payer.

19. Participant understands that this Initiative is offered for a limited time and for a limited number of patients, and Palette reserves the right to change or terminate the Initiative at any time, in whole or in part, without prior notice.

20. Participant acknowledges that the Initiative may limit the number of patients that may be enrolled in the Initiative each month and agrees not to exceed the established limit without prior approval from the Initiative.

21. Participant agrees to notify Palette upon receipt of any payment received from payer related to the Product for enrolled patients for which an invoice credit has already been issued by the Initiative.

22. Participant will not disclose information about this Initiative or market this Initiative, including the patients enrolled and Participant's participation in the Initiative, to any

outside parties external to or not affiliated with the physician's practice, unless required by law or regulation.

23. The undersigned physician(s) certifies that he/she/they is/are authorized to act on behalf of the above listed physician practice.

24. This agreement shall terminate on December 31, 2022, unless terminated earlier. Either Party may terminate this Agreement upon fifteen (15) days prior written notice to the other Party.

Please sign below to acknowledge acceptance of the described Temporary Rebate Initiative terms and conditions.

Participant
Signature: _____
Name: _____
Practice: _____
Title: _____
Date: _____

PALETTE

Signature: 
Printed Name: James Leech
Title: Head of Strategy & Corporate Development
Date: November 19, 2020

Please Fax Signed Request Form to:
FAX: **1-513-506-7361**