Supply Chain Management
Policy Number: 641

CLINICAL QUALITY PRODUCT VALUE ANALYSIS POLICY

Purpose:

The purpose of this Clinical Quality Product Value Analysis (CQPVA) Policy is to establish an organized, systematic, data driven, evidence based, and multidisciplinary approach in the selection of clinical products and supplies, technology, and non-capital equipment while supporting and complementing patient and healthcare worker safety, quality practices, improved outcomes, process improvement, and financial stewardship for Covenant HealthCare.

This policy describes the process for requesting, evaluating, and implementing new or alternative product into hospital that promotes optimal balance of quality, patient outcomes, cost effectiveness, as well as supports standardization and utilization efforts.

Definitions

Capital – refers to product that costs more than $5000 and is designed for reuse for an extended period of up to 3 years or more.

Disposables – refers to product that is single use or does not meet the capital expense or usable life definition and is discarded after use.

Evaluation – term used interchangeably with "trial" to describe the process undertaken to assess whether a new product adds value to patient care.

Implants – refers to product that is single patient use and implanted into patients.

Instruments – Instruments are either
- **Reusable** – meaning they are subject to re-sterilization after use. If an instrument costs more than $200 and is reusable, it is also minor equipment.
- **Disposable** – meaning they are single patient use and considered disposable
- **Reposable** – meaning they can be reused for a pre-defined number of uses, then discarded

Medical Grade – FDA approval for use in clinical setting usually with 510K documentation

New – describes any product not approved for use at hospital or without prior utilization. New products may also include capital equipment, disposables, implants and instrumentation.

Inclusive in this definition of new product are sizes of product other than those approved and stocked at hospital when the price has significantly increased.

New Technology/High Financial Impact (NT/HFI) – describes new innovative product that radically alters the way healthcare is produced or performed. This type of product can introduce an entirely new procedure, patient population, and hospital revenue to hospital.

This term also describes a product that adds $500 or more in cost per procedure, or will contribute an additional $25,000 expense to the hospital per year.

Products that have less than 12 months FDA approval that are not an update of an existing product or technology.

NTAC- New Technology Advisory Council

Product – refers to all capital equipment, disposables, implants and instrumentation.

Requestor - individual completing the product request eform. This might not be the individual that will use the product. For example: the primary service nurse may complete a request for a surgeon. Vendor representatives are not authorized to complete or submit requests on behalf of clinicians.

Sponsor – the clinician who will be the end-user of the requested product.

Policy: All products used at Covenant HealthCare will be subject to this policy. Any product introduced without a purchase order and/or prior approval through the CQPVA will be considered a donation.

Decisions made through the CQPVA process will include:

1. Clinical problem evaluation and product criteria identification.
2. Clinical evidence to support the product request (Preferably not clinical evidence from the manufacturer of the product).
3. Analysis of new products prior to adoption.
4. Documentation of clinical efficacy for new products.
5. Analysis of cost reduction opportunities achieved through supply standardization, utilization, and process improvement.
6. Cost, /return on investment, and potential reimbursement impact analyses.
7. Use of a clinical evidence evaluation tool.

Key areas that use the CQPVA process include, but are not limited to:

1. Cardiovascular Services
2. Interventional Radiology/Imaging
3. Surgical Services

4. Laboratory
5. Pulmonary/Respiratory
6. Emergency Department
7. Nursing Services
8. Support services area

The CQPVA Team's function is to review and evaluate products for utilization that will best meet the needs of patients and staff at Covenant HealthCare. Major components of the process include:

1. Selection of products that meet or exceed requirements of performance, quality, safety, and cost effectiveness.

2. Reduction of cost through contract negotiations, standardization and proper utilization of products and equipment.

3. Measurement of clinical and financial outcomes as appropriate for selected items.

Procedure: Clinical Quality Product Value Analysis Processes

New Initiative or Product Request

1. All new initiative and product requests must go through the Clinical Quality Product Value Analysis process prior to use at Covenant HealthCare.
2. Exceptions to this policy will be:
    a. Investigational drugs and devices that are being evaluated through the Institutional Review Board (IRB) process.
    b. Replacement parts for existing equipment.
3. All new initiative and product requests should be routed directly to the CQPVA Administrator for initial review.
4. Product requests that go to CQPVA require at least 21 business days to process due to evaluating clinical evidence, reimbursement, contract assessment(s), inventory, storage, and cost impacts to the organization.

Notwithstanding meeting qualification of preceding requirement, initiative is not guaranteed to be evaluated at nearest committee meeting. Capacity of committee will determine date and time of initiative evaluation.

5. Complete the CQPVA- Initiative Scorecard. (See addendum A)
6. The CQPVA- Initiative Scorecard will generate a recommended product decision based on categorical criteria on a scale (0-27).

a. Requests can be approved, denied, or deferred.
b. If a request has been denied the requestor can initiate the appeal process (see below).

8. Cases should not be scheduled prior to product approval confirmation from CQPVA stating the request has received the appropriate review. Cases scheduled without advance approval may be subject to cancellation and will be reported to Risk Management and Patient Safety and Quality Teams.

New Tech/High Financial Impact Process (NT/HFI)

1. Refer to the established CQPVA product request process for New Tech/High Financial requests.
2. The NTAC will review all NT/HFIP requests once a month.
3. Any New Technology that generates new procedures, patient population or hospital revenue to the organization would be reviewed through an established new business pro forma process.

New On-Boarding Physicians

1. New physicians will review a Covenant HealthCare product menu that lists the current products that are available.
2. If there are new requested products that are functionally equivalent to products that already exist at Covenant HealthCare, then the requestor must bring the new product request through CQPVA for review, and approval or declination.

Medical Resident and/or Clinical Intern Product Request or Initiative

1. Initiatives or Product Requests made by Medical Residents and/or Clinical Interns must have sponsorship by an Attending Privileged Physician and/or Covenant Employed Clinical Staff.
2. Attending Privileged Physicians and/or Covenant Employed Clinical Staff that sponsor a Medical Resident and/or Clinical Intern product request or initiative must champion and attend the respective CQPVA Meeting and is responsible for adherence to all elements of the "New Initiative or Product Request" section of the CQPVA Policy 641.

Clinical Quality Product Value Analysis Evaluation

1. The CQPVA Administrator will assign a CQPVA Team to evaluate and document the following during its deliberations:
    a. Clinical need or problem to be solved
    b. Documentation of current product related issue
    c. Reason for request
    d. Stakeholder input
    e. Objective clinical requirements
    f. Evaluation/validation documentation (see detail below)

g. Pre and post clinical measurements for the evaluation/validation to ensure predicted outcomes
h. Related research or regulatory requirements
i. Education needs related to validation and/or implementation
j. All communication
k. Financial impact including reimbursement

2. Once a full evaluation has been completed, the CQPVA Team will make a decision related to the initiative request; this can include a full or limited adoption, evaluation for a defined period of time, postponement, decline, etc. and may be presented to the Steering team for final approval.
3. The decision may be appealed by the Requestor to the CQPVA Steering Team in person.
4. Decisions are based on the voting structure that is standard to all Teams.

Resubmission of inactive products (two years or >) through CQPVA

1. Any requests for previously used product(s), whether Covenant-owned / managed, vendor consigned and/or brought in case-by-case, that have been inactive for two (2) years or greater, must be submitted / resubmitted through the respective CQPVA Team.
   a. There may be several reasons why product(s) become inactive, i.e., manufacturer discontinues, physician / staff member leaves organization, etc.
   b. The intent is to reevaluate, in the current environment, potential impacts to clinical outcomes, existing / pending contracts, storage / inventory space availability, and reimbursement.

Evaluation/Validation

1. In the event that a product evaluation is approved, the following will be in place prior to initiation of the evaluation:
   a. All participants have been properly trained and in-serviced.
   b. Vendors will not participate in a CQPVA evaluation unless it is required for the requested product (i.e., in-service or training).
   c. An evaluation form containing objective non-financial criteria will be developed, evaluation timeframe defined, and methodology approved by the CQPVA Team.
   d. Prior to actual evaluation appropriate safety checks will be conducted by individual departments.

Final Decision Process

1. Respective CQPVA Teams make the decisions for a product request.
2. The CQPVA Administrator will communicate the decision to the requestor.
3. Declined requests have the right to appeal through the Appeals Process.

Appeals Process

1. Requests that are denied are not reviewable again for 1 year from the decision.
2. The requestor/sponsor may appeal the denial earlier if there is a significant change in the available clinical or financial evidence to where reconsideration would be warranted.
3. The appeal request will be reviewed by the CQPVA Team that the original request was submitted for final dispensation.

Initiative Implementation

1. Supply Chain Management (SCM) will note and coordinate changes for approved products as follows:
    a. Validate best possible pricing and service based upon a bid, group purchasing contract and/or benchmark data.
    b. Place item in Item Master per policy and procedure.
    c. Place item into other databases as required.
    d. Contract Analyst will record fiscal impact on the team monthly report.
2. The CQPVA Administrator
    a. Coordinates procurement of item or service in collaboration with the CQPVA team and SCM.
3. The CQPVA Team will coordinate the following:
    a. Conduct follow up utilization measurement to validate actual versus predicted outcome
    b. Contract Analyst will monitor and record savings on the team monthly report.
    c. SCM will manage the conversion checklist to ensure a full and timely conversion of products.

Emergency Product Approval for One Time Use

1. The Director of Supply Chain Management will be notified when a product is being requested for a one time or emergency need.

2. Emergency use will be considered for consumable and or clinical products requested for an urgent patient need with possible adverse clinical outcome if not made available.

3. The use of the Emergency product can also be approved by a senior administrator prior to use.

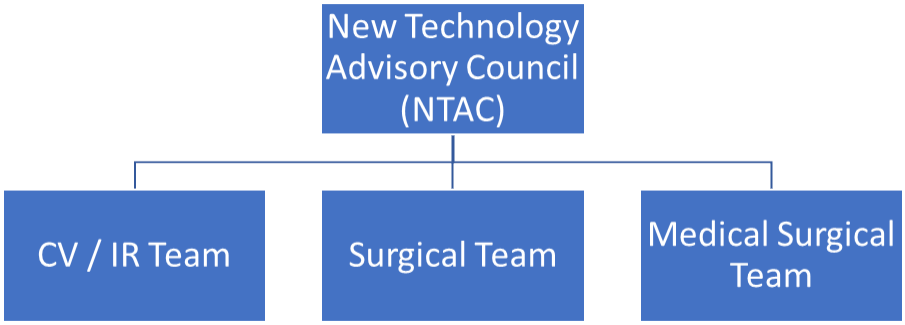
4. A record will be kept for each request to include the vendor, product, physician, rational for use, and approving administrator.

5. Any product used within Covenant HealthCare for an emergency situation will be automatically submitted to the CQPVA process for evaluation.

6. Products that are not introduced through the Emergency product process will be considered a donation to the organization and will not be billed to the patient or their insurance provider unless the product is ordered by Supply Chain Management one week prior to the procedure.

7. Emergency use will not be utilized to "try" a product prior to submitting to CQPVA process.

Clinical Quality Product Value Analysis Organizational Structure



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Reviewed by: Supply Chain Management – March 2018, July 2021
Executive Team – September 2015, October 2021

Approval:

_____ December 2021
Michael Sullivan, MD – Vice President Quality Impr/CMO Date

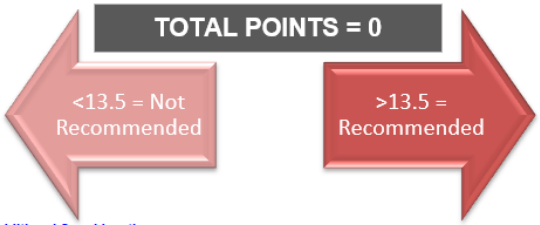
_____ December 2021
Kevin Albosta – Vice President Consulting Services/CFO Date

ADDENDUM A

Covenant CQPVA - Initiative Scorecard

Product Request: _____
Requestor: _____
Date: _____
FDA Approval: _____

Financial Analysis	
Revenue Impact	$ -
Product Cost:	
Est. Ann. Vol:	
Est. Ann. Cost:	
Current Ann. Cost:	
Est. Annual Impact (Net)	



Additional Considerations: _____

Clinical Evidence & Benefits	Financial Impact	Service Line Impact	Supply Chain Goals & Strategic Plan
Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.	Increased Reimbursement	Consensus Among Peers	Promotes product standardization
Evidence of ↓ Length of Stay	Cost impact	Physician/Staff Ease of Use	Promotes ability to optimize supply contracts
Evidence of ↓ Infections / Complications		Improves Patient/Staff Safety	Decreases # of SKUs / # of SKUs remain neutral
Evidence of ↓ Readmissions			Compliant with current contracts

Clinical Evidence & Benefits		
Quality Evidence	No Evidence submitted with request	0
	Evidence submitted is sponsored from vendor or biased source	1
	Published evidence from agnostic source.	2
Evidence of Reduced LOS	No Evidence submitted with request	0
	Decreased LOS evidence submitted is sponsored from vendor or biased source	1
	Decreased LOS evidence published from agnostic source	2
Evidence of Reduced Infections/Complications	No Evidence submitted with request	0
	Decreased complications/infections evidence submitted is sponsored from vendor or biased source	1
	Decreased complications/infections evidence published from agnostic source	2
Evidence of Reduced Readmissions	No Evidence submitted with request	0
	Decreased readmissions evidence submitted is sponsored from vendor or biased source	1
	Decreased readmissions evidence published from agnostic source	2
Financial Impact		
Increased Reimbursement	No change or decrease in reimbursement	0
	Increase of 5% or less in reimbursement	1
	Increase in excess of 5% in reimbursement	2
Increased Reimbursement	Increases cost of procedure or supply	0
	Cost neutral	1
	Decreases cost of procedure or supply by 5% or less	2
	Decreases cost of procedure or supply in excess of 5%	3

Service Line Impact		
Consensus Among Peers	No peers have supported or indicated interest in use/conversion	0
	Partial support/interest from discipline	1
	Full agreement of adoption/conversion	2
Physician/Staff Ease of Use	No change to procedure/patient care time	0
	Decreases procedure/patient care time	2
Patient/Staff Safety	No change to patient/staff safety	0
	Increases patient/staff safety	2
Supply Chain Goals & Strategic Plan		
Promotes Product Standardization	No change in number of vendors within product category	0
	Reduction of vendors within product category	1
	Full (90%+) standardization within product category	2
Promotes ability to optimize supply contracts	No change or hinders current marketshare	0
	Drives compliance toward current contracts	2
Decreases # of SKUs	No change or addition of SKUs to maintain	0
	Reduces number of SKUs to maintain	2
Compliant with current contracts	Initiative hurts current contract compliance	0
	Increases compliance with current contract commitments	2